Supreme Court, U.S.
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No. 99-

IN THE

Supreme Court of the United States

GENERAL PUBLIC UTILITIES CORPORATION, *et al.*,

Petitioners,

v.

FRED N. ABRAMS, *et al.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

The trial court consolidated for pretrial purposes this "mass tort" litigation arising out of the 1979 Three Mile Island accident, and set schedules for the completion of fact and expert discovery. After discovery was closed, the district court determined that much of the expert testimony proffered on behalf of all the plaintiffs was inadmissible under this Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and granted summary judgment dismissing all the plaintiffs' claims. The Court of Appeals for the Third Circuit reversed, holding that the Seventh Amendment prevented summary judgment against the plaintiffs in the consolidated proceedings whose claims had not also been designated for a planned "test case" trial, because they had not made a "positive manifestation of agreement" to participate in the summary judgment proceedings.

The question presented is whether there is any basis for the Court of Appeals' holding that in the absence of a "positive manifestation of agreement" by a plaintiff to participate in summary judgment proceedings, the Seventh Amendment guarantee of the right to a trial by jury precludes the entry of summary judgment against that plaintiff.

LIST OF ALL PARTIES TO THE PROCEEDING BELOW AND CORPORATE DISCLOSURE STATEMENTS

A. Petitioners

The following companies are petitioners (all defendants/appellees in the courts below):

General Public Utilities Corporation; Metropolitan Edison Company; Jersey Central Power & Light Company; Pennsylvania Electric Company; McDermott Incorporated (previously known and identified as J. Ray McDermott & Company); Raytheon Constructors Inc. (previously known and identified as Catalytic, Inc.); Burns & Roe Enterprises, Inc.; and Dresser Industrial Valve and Instrument Division of Dresser Industries, Inc.

B. Respondents

The respondents, plaintiffs/appellants in the courts below, are listed in J. App. 684a-747a. In addition, The Babcock & Wilcox Company, Inc.,[1] is being served as a respondent herein.

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1. Not participating as a petitioner because of the "automatic stay" set forth in Bankruptcy Code § 362, 11 U.S.C. § 362, as a consequence of the bankruptcy proceedings captioned *In re The Babcock & Wilcox Company, Inc., et al.*, Case No. 00-10992, in the United States Bankruptcy Court for the Eastern District of Louisiana.

C. Rule 29.6 Statements

Metropolitan Edison Company, Jersey Central Power & Light Company, and Pennsylvania Electric Company, are each wholly-owned subsidiaries of General Public Utilities Corporation. No publicly held company owns 10% or more of the stock of General Public Utilities Corporation.

McDermott Incorporated is a wholly-owned subsidiary of McDermott International, Inc. The Prudential Insurance Company of America owns more than 10% of the stock of McDermott International, Inc.

Burns & Roe Enterprises, Inc. is a wholly-owned subsidiary of Roe Enterprises, Inc., which is a wholly-owned subsidiary of Winona Hudson Corporation, which is a wholly-owned subsidiary of Warwick and York, Inc. No publicly held company owns 10% or more of the stock of Warwick and York, Inc.

Raytheon Constructors Inc. is a wholly-owned subsidiary of Raytheon Constructors International, Inc., which is a wholly-owned subsidiary of Raytheon Engineers & Constructors International, Inc., which is a wholly-owned subsidiary of Raytheon Company. Franklin Resources, Inc. owns more than 10% of the stock of Raytheon Company.

Dresser Industries, Inc. is a wholly-owned subsidiary of Halliburton Company. No publicly held company owns 10% or more of the stock of Halliburton Company.

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9 Wright & Miller, Federal Practice and Procedure: Civil 2d § 2382 (1995) 7

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10 C.F.R. § 20.1004 (1997) 5

Petitioners respectfully request that a writ of certiorari be issued to review the judgment of the Third Circuit Court of Appeals in this case.

OPINIONS BELOW

All of the following opinions[2] are published: *In re TMI Litigation*, 193 F.3d 613 (3d Cir. 1999) (J. App. 1a); *In re TMI Litigation*, 199 F.3d 158 (3d Cir. 2000) (J. App. 275a); *In re TMI Litig. Cases Consol. II*, 910 F. Supp. 200 (M.D. Pa. 1996) (J. App. 664a); *In re TMI Litig. Cases Consol. II*, 911 F. Supp. 775 (M.D. Pa. 1996) (J. App. 537a); *In re TMI Litig. Cases Consol. II*, 922 F. Supp. 997 (M.D. Pa. 1996) (J. App. 394a); *In re TMI Litig. Cases Consol. II*, 922 F. Supp. 1038 (M.D. Pa. 1996) (J. App. 497a); *In re TMI Litig. Consol. Proceedings*, 927 F. Supp. 834 (M.D. Pa. 1996) (J. App. 295a).

JURISDICTIONAL STATEMENT

Jurisdiction to review the decision by the United States Court of Appeals for the Third Circuit dated November 2, 1999, the timely petition for rehearing of which was denied by order dated January 4, 2000 (J. App. 682a), is conferred by 28 U.S.C. § 1254(1).

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2. Since both the petitioners and respondents are filing petitions for writ of certiorari in this matter, a separate bound Joint Appendix (J. App.) is being filed herewith.

CONSTITUTIONAL PROVISION INVOLVED

United States Constitution, Seventh Amendment:

> In suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise reexamined in any Court of the United States, than according to the rules of the common law.

STATEMENT OF THE CASE

Petitioners, defendants below, were sued by more than 2000 individuals who had been in the vicinity of the Three Mile Island (TMI) nuclear plant around the time of the 1979 accident there. Plaintiffs claimed that radiation released in that accident caused them to develop one or another disease, including cancers, benign tumors, or other health problems. Those suits were commenced at varying times, primarily in the mid 1980s. Most of the suits were commenced in Pennsylvania state court, where they were consolidated for pretrial proceedings by order of the Court of Common Pleas of Dauphin County, Pennsylvania. Hundreds of the plaintiffs in those Pennsylvania suits, anticipating a problem under Pennsylvania's two year statute of limitations, also commenced actions in federal court in Mississippi based on diversity jurisdiction, in an effort to secure the benefit of that state's six year statute of limitations for personal injury actions.[3] Those actions were transferred to the federal court

3. *Cf. Ferens v. John Deere Co.*, 494 U.S. 516 (1990) (under Mississippi choice of law rules, Mississippi statute of limitations would apply to actions commenced in Mississippi, even though (Cont'd)

in the Middle District of Pennsylvania pursuant to 28 U.S.C. § 1404(a). Those plaintiffs also filed an additional action in Mississippi state court, naming a non-diverse defendant, as a further protective effort.

Because these suits involve claims that radioactive material released in the TMI accident caused personal injury, they are "public liability actions" within the Price-Anderson Act which, as amended in 1988, created federal jurisdiction for all public liability actions. *See* 42 U.S.C. § 2014(hh) (definition of "public liability action"), 42 U.S.C. § 2210(n)(2) (federal jurisdiction for "public liability actions"). Pursuant to those 1988 amendments, defendants removed all the then pending state court actions, both Pennsylvania and Mississippi, to the Middle District of Pennsylvania.

After a hiatus during which the constitutionality of the 1988 Price-Anderson amendments was determined, the District Court for the Middle District of Pennsylvania made several procedural orders. So far as the question presented here is concerned, the important ones were:

1. All orders previously entered in any of the pending actions were deemed to have been entered in the Middle District. By this order, the consolidation for pretrial proceedings effected in Pennsylvania state court was expressly continued in the federal action, just as it had effectively been transported by 28 U.S.C. § 1450 (all orders

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(Cont'd)
plaintiff and defendant were domiciled elsewhere and accident occurred elsewhere; Mississippi limitations period would apply following transfer to forum where plaintiffs resided and accident occurred).

prior to removal "remain in full force and effect until dissolved or modified by the district court").

2. To eliminate the multiplicity of suits by the same individuals, and streamline the multiplicity of different civil actions, all the actions but one were dismissed pursuant to stipulation of counsel, and every plaintiff in every action was thereafter to be treated as a plaintiff in the one consolidated action.

3. A protocol was established to differentiate, in the one consolidated action, between pleadings applicable to all plaintiffs, and pleadings applicable to just a few plaintiffs: if a pleading related to all plaintiffs, it was to so state in the caption; if a pleading related to one or an identified subset of plaintiffs, it was to identify the counsel for those plaintiffs on the first page of the caption, and to list the individual plaintiffs on a second page of the caption.

4. The court established deadlines applicable to "all plaintiffs" for discovery, including the submission of expert reports pursuant to Fed. R. Civ. P. 26(a)(2).

5. The court adopted a "test case" approach for trial, pursuant to which counsel for all plaintiffs were to select six cases for an initial trial, and counsel for defendants were also to select six plaintiffs for that initial trial. In effect, the court "severed" for trial the claims of the twelve plaintiffs so selected from the mass of over two thousand plaintiffs, while in all other respects the litigation proceeded as a single consolidated case.

Following entry of these orders, plaintiffs' counsel filed and served, as applicable to all plaintiffs, a number of expert

reports. Plaintiffs' "dose" experts opined that the accident had caused people in the vicinity of Three Mile Island to receive doses of one hundred or more rems.[4] Plaintiffs' medical causation experts opined that if plaintiffs received a dose of ten rems or more, such a dose more likely than not caused their cancers or neoplasms.

The district court set a schedule, applicable to "all plaintiffs," for any *in limine* motions directed to proposed expert testimony, and consequent summary judgment motions. Defendants filed *in limine* motions directed to most of plaintiffs' experts, and the district court, after extensive hearings, largely granted those motions as to the dose experts. J. App. 394a, 497a, 537a, 664a. Defendants then filed a motion for summary judgment applicable to "all plaintiffs." Defendants argued that because the *in limine* rulings rendered "all plaintiffs" unable to prove that they had been exposed to any appreciable radiation, and because the causation expert opinions were expressly contingent on proof that each plaintiff had received a dose of ten rems or more, plaintiffs would be unable to make out a prima facie case. All plaintiffs, through their counsel, opposed the motion. They did not interpose an affidavit pursuant to Fed. R. Civ. P. 56(f), stating what additional affidavits or discovery (the deadline for which had passed in any event) they needed to oppose the motion.

The district court agreed with defendants' argument and entered summary judgment dismissing the claims of all plaintiffs. J. App. 295a.

On appeal, the Court of Appeals for the Third Circuit affirmed the district court's rulings excluding most of

4. A "rem" is defined in 10 C.F.R. § 20.1004 (1997).

plaintiffs' proffered expert testimony, and affirmed the entry of summary judgment dismissing the claims of the "test case" plaintiffs. J. App. 1a.

The Court of Appeals ruled, however, that the Seventh Amendment prevented dismissal of the claims of all the other plaintiffs. It wrote:

> . . . The extension of the summary judgment decision to the Non-Trial Plaintiffs implicates their Seventh Amendment jury trial rights. Summary judgment does not violate a party's Seventh Amendment jury trial rights so long as the person having the right to the jury trial is an actual participant in the summary judgment proceeding. . . . However, absent a positive manifestation of agreement by Non-Trial Plaintiffs, we cannot conclude that their Seventh Amendment right is not compromised by extending a summary judgment against the Trial Plaintiffs to the non-participating, non-trial plaintiff. In fact, a Seventh Amendment argument was made in the District Court, but the argument was summarily dismissed.

J. App. at 263a-64a. (citations omitted).[5]

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5. The Court of Appeals' reference to the "non-participating, non-trial plaintiff" is puzzling. Counsel for all plaintiffs were served with all motions and briefs designated as applicable to "All Plaintiffs," and with all Orders establishing deadlines applicable to "All Plaintiffs." Pursuant to Fed. R. Civ. P. 5(b), service upon a party represented by an attorney "shall be made upon the attorney

(Cont'd)

ARGUMENT

The decision below erects an impediment to, and thereby compromises the utility of, two important procedural devices. The device of consolidation for pretrial purposes is recommended by the *Manual for Complex Litigation, Third*, for "all related cases pending or which later may be filed in the same court. . . ." § 20.123 (3rd ed. 1995). "Pretrial proceedings in these cases *should be* coordinated or consolidated under Fed. R. Civ. P. 42(a). . . ." *Id.* (emphasis added). The *Manual* identifies "mass tort litigation" as a type of case exampling the need for effective judicial management, to "help control cost and delay fairly." *Id.* at § 10.1. *See also* 9 Wright & Miller, Federal Practice and Procedure: Civil 2d § 2382 (1995) ("Consolidation of actions in their pretrial stage, under many circumstances, will be a desirable administrative technique and is within the power of the court.").

Even more important is the "traditional authority of trial judges to grant summary judgment in meritless cases." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986) (quoting Bork, Circuit Judge, dissenting below, *Catrett v. John-*

(Cont'd)
unless service upon the party is ordered by the court." No such order requiring service upon the parties, rather than their attorneys, was made here.

Similarly, the Court of Appeals' characterization of the district court's having "summarily dismissed" the plaintiffs' Seventh Amendment argument implies that the district court had not given the issue the attention it deserved. As is shown next, however, the plaintiffs' Seventh Amendment argument was without any basis, and therefore the district court was correct in rejecting that argument without extensive discussion.

Mansville Sales Corp., 756 F.2d 181, 187 (D.C. Cir. 1985)). In *Celotex* this Court observed that "[o]ne of the principal purposes of the summary judgment rule is to isolate and dispose of factually unsupported claims. . . ." *Id.* at 323-24. Indeed, this Court wrote:

> Summary judgment procedure is properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the Federal Rules as a whole, which are designed "to secure the just, speedy and inexpensive determination of every action."

Id. at 327 (citation omitted).

Celotex also established that the twin protections to which the target of a summary judgment motion is entitled are (1) "notice that she had to come forward with" evidence opposing the motion, and (2) an opportunity to conduct discovery, secured by the Rule 56(f) affidavit, in order to protect against being "railroaded" by a premature motion. *Id.* at 326.

That both Fed. R. Civ. P. 42 and 56 were properly invoked by the district court here can hardly be gainsaid. All the pending actions involved claims that a single event — the March, 1979 accident at the Three Mile Island Unit 2 nuclear reactor — caused plaintiffs' various health problems. Use of Fed. R. Civ. P. 42(a) to consolidate these multiple actions for pretrial purposes, when they all arose out of the same event, represented a paradigmatic application of that rule.

Similarly, the summary judgment motion was hardly "premature," since the consolidated actions had been open to discovery for nearly a decade, J. App. at 255a, and by the time of the motion, discovery was closed for all plaintiffs. *Id.* at 267a. In addition, all plaintiffs were on notice that defendants' summary judgment motion was directed to them, since it was captioned as applicable to "all plaintiffs." *Id.* at 22a-23a. And as the Court of Appeals' opinion acknowledged, plaintiffs' opposition to the motion included a Seventh Amendment argument on behalf of the Non-Trial Plaintiffs. *Id.* at 264a (citing 927 F. Supp. at 838 n.7) (J. App. at 302a n.7).[6]

To require a record that also reflects each plaintiff's "positive manifestation of agreement," *id.*, to submit to the summary judgment procedure imposes a burden that is as unlikely of fulfillment as it is unauthorized by any of the Rules adopted by this Court's orders promulgating or amending the Federal Rules of Civil Procedure. No plaintiff would offer "positive manifestation of agreement" to submit to summary judgment procedures, when that plaintiff's singular goal is to get his or her case, however unfounded, before a jury. Every plaintiff desiring to resist a summary judgment motion would likely avail himself or herself of the simple expedient of refraining from supplying a "positive manifestation of agreement" to submit to the Rule 56 procedure. This, undoubtedly, is why the Federal Rules of Civil Procedure make no mention whatsoever of such a requirement.

---

6. Inasmuch as "all plaintiffs" submitted expert reports, briefed the *in limine* motions, and briefed the summary judgment motion, it is perplexing, as noted above, why the Court of Appeals characterized the non-trial plaintiffs as "non-participating."

Nor does any prior decision from this Court, or any other Court of Appeals, even hint at such a requirement. The standard created by the Court of Appeals for the Third Circuit, in the decision below, would effectively revoke Rule 56 for that Circuit, in cases consolidated under Rule 42. But only this Court has such authority under the Rules Enabling Act, 28 U.S.C. § 2072.

Moreover, Congress itself intended, in creating federal jurisdiction for all public liability actions, that such actions would thereby receive the benefit of consolidation and coordination in accordance with the Federal Rules of Civil Procedure:

> The availability of the provisions for the consolidation of claims in the event of any nuclear accident . . . would avoid the inefficiencies resulting from duplicative determinations of similar issues in multiple jurisdictions that may occur in the absence of consolidation.

S. Rep. No. 100-218, at 13 (2nd Sess. 1988), *reprinted in* 1988 U.S.C.C.A.N. 1476, 1488.

The decision by the Court of Appeals, which gives plaintiffs' counsel a right to veto the Federal Rules of Civil Procedure, if they choose, thus presents such a departure from the "accepted and usual course of judicial proceedings . . . as to call for an exercise of this Court's supervisory power." S. Ct. R. 10(a). No other court presiding over mass tort litigation consolidated for pretrial proceedings has ever required that a plaintiff must somehow exhibit a "positive manifestation of agreement" to be bound by discovery deadlines, discovery submissions, *in limine* rulings, or

summary judgment proceedings, before the Seventh Amendment permits entry of a summary judgment against that plaintiff. When that plaintiff has notice of all applicable proceedings, through notice to his or her counsel; when that plaintiff, through counsel, submits expert witness reports in the consolidated discovery process; when that plaintiff, through counsel, receives notice that a motion for summary judgment has been filed seeking dismissal of that plaintiff's claim; when that plaintiff, through counsel, appears and opposes the motion; in these circumstances, there should be no doubt that the Seventh Amendment does not prevent use of the summary judgment device for the dismissal of unsupportable claims.

Review is necessary then, not just because of the inefficiency imposed on this litigation, already well over a decade old, and involving thousands of plaintiffs. Review is also necessary so that other district courts, in this period of increasing docket pressure, are not denied access to the efficiency-enhancing procedural devices which the Rules of Civil Procedure adopted by this Court have intended them to have.

CONCLUSION

The Petition for Writ of Certiorari should be granted, and the decision of the Court of Appeals for the Third Circuit reversing summary judgment as to the "Non-Trial Plaintiffs" should receive plenary review.

Respectfully submitted,

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ON PETITIONS FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

APPENDIX

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In re TMI LITIGATION

Lori Dolan; Joseph Gaughan; Ronald Ward; Estate of Pearl Hickernell; Kenneth Putt; Estate of Ethelda Hilt; Paula Obercash; Jolene Peterson; Estate of Gary Villella; Estate of Leo Beam,

Appellants No. 96-7623.

In re TMI Litigation

All Plaintiffs Except Lori Dolan, Joseph Gaughan, Ronald Ward, Estate of Pearl Hickernell, Kenneth Putt, Estate of Ethelda Hilt, Paula Obercash, Jolene Peterson, Estate of Gary Villella and Estate of Leo Beam,

Appellants No. 96-7624.

In re TMI Litigation

All Plaintiffs; Arnold Levin; Laurence Berman; Lee Swartz

Appellants No. 96-7625.

Nos. 96-7623, 96-7624, 96-7625.

United States Court of Appeals,
Third Circuit.

Appendix A

ARGUED: June 27, 1997

Opinion filed: Nov. 2, 1999

* * *

Before: GREENBERG and McKEE, Circuit Judges, and GREENAWAY, District Judge.*

McKEE, Circuit Judge

---

* The Honorable Joseph A. Greenaway, Jr., United States District Court Judge for the District of New Jersey, sitting by designation.

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Appendix A

OPINION OF THE COURT

I. INTRODUCTION

These three appeals arise out of the nuclear reactor accident which occurred on March 28, 1979, at Three Mile Island in Dauphin County, Pennsylvania.[1] Two of the appeals concern the personal injury claims of more than 2,000 Three Mile Island area residents who allege that they have developed neoplasms[2] as a result of the radiation released into the environment as a result of the reactor accident. The first appeal is that of a group of ten trial plaintiffs who were selected by the parties after the District Court adopted the plaintiffs' case management order, which called for a "mini-trial" of the claims of a group of "typical" plaintiffs (the "Trial Plaintiffs"). The critical issue there is the trial plaintiffs' ability to demonstrate that they were exposed to doses of radiation sufficient to cause their neoplasms. Proof

---

1. Sometime prior to argument, the appellees moved to consolidate these appeals. We denied that request by order dated December 24, 1996. We did, however, instruct the Clerk to list these three appeals before a single merits panel. We now believe that the most expeditious way to dispose of these appeals is to consolidate them and dispose of them in one opinion. Therefore, we have entered an order consolidating these three appeals.

2. A neoplasm is "an abnormal tissue that grows by cellular proliferation more rapidly than normal and continues to grow after the stimuli that initiated the new growth cease. N[eoplasm]s show partial or complete lack of structural organization and functional coordination with the normal tissue, and usually form a distinct mass of tissue which may be either benign or malignant." STEDMAN'S MEDICAL DICTIONARY 931 (26th ed.1995).

of that causation depended on the admissibility of the testimony of several experts that the Trial Plaintiffs retained. These experts attempted to testify about the amount of radiation released into the environment by the nuclear reactor accident, and thereby correlate the plaintiffs' neoplasms to that accident.

Defendants challenged the admissibility of the experts' testimony and the District Court was therefore required to hold extensive in limine hearings pursuant to its "gatekeeping" role under Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993). Following those hearings, the court excluded the overwhelming majority of the Trial Plaintiffs' proposed expert testimony as to dose exposure. Following the exclusion of the dose exposure testimony, the defendants moved for summary judgment alleging that Trial Plaintiffs could not establish causation absent the excluded expert testimony regarding dose.

The District Court agreed and held that, as a result of its rulings under Daubert, Trial Plaintiffs were unable to connect their neoplasms to the TMI accident. Accordingly, the court granted summary judgment in favor of defendants and against the Trial Plaintiffs. In re TMI Litigation Consolidated Proceedings, 927 F.Supp. 834 (M.D.Pa.1996). The District Court then reasoned that its Daubert rulings would be binding on all of the other plaintiffs, i.e., the Non-Trial Plaintiffs, if there were evidentiary issues common to all plaintiffs, Id. at 837. Therefore, the court therefore extended its Trial Plaintiff summary judgment decision to the Non-Trial Plaintiffs, and granted summary judgment to the defendants on all of the

claims of the approximately 2,000 remaining TMI personal injury plaintiffs. The propriety of that extension is the subject of the second appeal.

The third and last appeal concerns the propriety of the District Court's imposition of monetary sanctions against certain of the plaintiffs' counsel for violations of pre-trial discovery requirements and orders. The sanctioned counsel have requested that the TMI personal injury litigation be reassigned to another trial judge upon remand, if we reverse the District Court in either or both of the first two appeals.

For the reasons that follow, we will affirm the grant of summary judgment to the defendants on the claims of the Trial Plaintiffs (No. 96-7623). We will, however, reverse the grant of summary judgment to the defendants on the claims of the Non-Trial Plaintiffs (No. 96-7624), but we will affirm the imposition of monetary sanctions and deny the request for reassignment (No. 96-7625).

II. PROCEDURAL HISTORY[3]

On March 28, 1979, radioactive materials were released into the environment as the result of an accident which occurred at Unit 2 of the Three Mile Island nuclear power generating station in Dauphin County ("TMI-2"). Three Mile Island is a small island in the Susquechanna River,

3. The procedural history of this litigation is almost as complicated as the scientific principles implicated by the Daubert challenges that we discuss below. However, an understanding of the procedural history is necessary to our discussion of the District Court's decision to grant summary judgment against the Non-Trial Plaintiffs as well as the Trial Plaintiffs.

approximately fifteen miles downstream from Harrisburg, Pennsylvania. Following the accident, thousands of personal injury and other-non-personal injury claims[4] were filed against the owners and operators of the nuclear facility.[5]

As noted, more than 2,000 plaintiffs filed claims for personal injuries[6] purportedly caused by exposure to the radioactive materials released during the accident. Some of these personal injury claims were originally filed in the early 1980's in state and federal district courts in Pennsylvania, New Jersey and Mississippi. The defendants removed the state court actions to federal district courts in Pennsylvania and New Jersey, under the authority of the Price-Anderson Act, Pub.L. No. 85-256, 71 Stat. 576 (1957).[7]

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4. The defendants have settled non-personal injury claims brought by individuals, businesses and non-profit organizations within a twenty-five mile radius of the TMI facility. See Stibitz v. General Public Utilities Corp., 746 F.2d 993, 995 n. 1 (3d Cir.1984).

5. The defendants are General Public Utilities, Inc., Metropolitan Edison Co., Jersey Central Power & Light Co., Pennsylvania Electric Co., Babcock & Wilcox, Co., McDermott Inc., Raytheon Constructors, Inc., and Burns & Roe Enterprises, Inc. They were, at the time of the accident, either the owners and operators of the facility or companies which had provided design, engineering and/or maintenance services to the owners and operators or vendors of equipment or systems installed in the facility. In re TMI Litigation Cases Consol. II, 940 F.2d 832, 836 (3d Cir.1991).

6. The personal injury plaintiffs allege that they have developed radiation induced neoplasms because of their exposure to ionizing radiation resulting from the TMI accident.

7. As we noted in In re TMI Litigation Cases Consolidated II, 940 F.2d 832, 837 n. 2 (3d Cir.1991), the Price-Anderson Act was

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enacted in 1957 as an amendment to the Atomic Energy Act of 1946, Pub. L. No. 79-585, 60 Stat. 755. The Atomic Energy Act was designed to establish an industry to generate inexpensive electrical power and it envisioned turning "atomic power into a source of energy" by turning "swords into plow shares." Pacific Gas & Electric Co. v. State Energy Resources Conservation & Development Commission, 461 U.S. 190, 193, 103 S.Ct. 1713, 75 L.Ed.2d 752 (1983). The Atomic Energy Act envisioned the nuclear energy industry as a government monopoly; however, Congress ultimately decided to permit the private sector to become involved. See Atomic Energy Act of 1954, Pub.L. No. 830-703, 68 Stat. 919. The 1954 Act "grew out of Congress' determination that the national interest would best be served if the Government encouraged the private sector to become involved in the development of atomic energy for peaceful purposes under a program of federal regulation and licensing." Pacific Gas & Electric Co., 461 U.S. at 206-07, 103 S.Ct. 1713. Nonetheless, the private sector was wary of the potential exposure it faced in the event of a nuclear accident because of the nature of nuclear energy. Thus, while assuring Congress that the risk of a major nuclear accident was low, "spokesmen for the private sector informed Congress that they would be forced to withdraw from the field if their liability were not limited by appropriate legislation." Duke Power Co. v. Carolina Environmental Study Group, Inc., 438 U.S. 59, 64, 98 S.Ct. 2620, 57 L.Ed.2d 595 (1978). In response, Congress enacted the Price-Anderson Act to protect the public and encourage the development of the atomic energy industry. In re TMI, 67 F.3d 1103, 1107 (3d Cir.1995) (citations and internal quotations omitted), cert. denied, 516 U.S. 1154, 116 S.Ct. 1034, 134 L.Ed.2d 111 (1996). The Price-Anderson Act limited the "potential civil liability of nuclear power plant operators and provided federal funds to help pay damages caused by nuclear accidents." Id. The Act requires nuclear facilities operators to purchase a specified amount of insurance from private carriers and further provides for government indemnification above the insurance

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Appendix A

After removal, the District Court for the Middle District of Pennsylvania ordered, inter alia, that all pending TMI personal injury cases in the Middle District be "consolidated for pretrial proceedings only." App. 13097. The District Court also ordered that the caption of every subsequent personal injury pleading should be identified as a personal injury claim. Id.

After we held that the Price-Anderson Act did not create a cause of action as a federal tort and was not intended to confer jurisdiction on federal district courts, see Stibitz v. General Public Utilities Corp., 746 F.2d 993, 997 (3d Cir.1984) and Kiick v. Metropolitan Edison Co., 784 F.2d 490, 493 (3d Cir.1986), the state court actions were remanded, and the federal court actions were transferred to the appropriate state courts. The cases originally removed to the Middle District of Pennsylvania, and those originally filed in the Middle District, were either remanded or transferred to the Court of Common Pleas of Dauphin County. Thereafter, in 1985 and 1986, the bulk of the personal injury claims which are the subject of this appeal were filed in the state courts.[8]

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amounts to an established aggregate limit on liability. In re TMI Litigation Cases Consolidated II, 940 F.2d at 837 n. 2. The Price-Anderson Act has been amended three times, most recently in 1988; yet the goal continues to be "to encourage private sector participation in the beneficial uses of nuclear materials." Id. at 853.

8. However, personal injury cases continued to be filed after 1986. The last case filed that is included in these appeals was Kline,
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On October 15, 1985, the Dauphin County Common Pleas Court entered a case management order. In that order, the Court of Common Pleas ordered that all cases be consolidated for pretrial purposes, and also required that all pleadings be captioned to identify which plaintiffs' group they applied to. That is, all personal injury cases received from the federal court were consolidated under the caption "Cases Consolidated I" and the cases filed in state court after our decision in Stibitz, were consolidated under the caption "Cases Consolidated II."

In 1988, Congress enacted the Price-Anderson Amendments Act of 1988, Pub.L. No. 100-408, 102 Stat. 1066. Those amendments to the Price-Anderson Act created a federal cause of action for "public liability actions"[9] and provided that all such suits arise under the Price-Anderson Act, 42 U.S.C. § 2014(h). The Act also provided for consolidation of such actions, including those already filed,

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et al. v. General Public Utilities Corp. et al., No. 1:CV 96-451 (M.D.Pa.), and it was filed on March 15, 1996. However, the latest personal injury case filed is Tyler et al v. General Public Utilities Corp. et al., No. 1:CV 96-1028 (M.D.Pa.), and it was filed on June 7, 1996. Brief of Appellants in No. 96-7624, at 6 n. 8. Apparently, Tyler is not included in this appeal.

9. The Price-Anderson Amendments Act defined a "public liability action" as "any suit asserting public liability." 42 U.S.C. § 2014(h). "Public liability" was defined as "any legal liability arising out of or resulting from a nuclear incident or precautionary evacuation," except for certain claims covered by workers' compensation, incurred in wartime or that involve the licensed property where the nuclear incident occurs. 42 U.S.C. § 2104(w).

in one federal district court. 42 U.S.C. § 2210(n).[10] Following enactment of that Act, the defendants removed all the pending state actions to the United States District Court for the Middle District of Pennsylvania.

Thereafter, the District Court for the Middle District of Pennsylvania conducted a case management conference. The personal injury cases known as "Cases Consolidated I" and "Cases Consolidated II" which had been removed from the Court of Common Pleas of Dauphin County were then pending in the Middle District along with the companion actions to the "Cases Consolidated II" which had been filed by forty-two plaintiffs in Mississippi federal and state court to take advantage of the more lenient Mississippi statute of limitations.[11] As a result of discussions during the conference, the District Court entered an order which required counsel to

> meet to streamline the record with an eye toward reducing the number of duplicative plaintiffs and suits, assigning fewer case numbers for the various actions, and deciding which cases needed

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10. We subsequently upheld the constitutionality of the retroactive application of the federal jurisdiction provisions of the Price Anderson Amendments Act. In re TMI Litigation Cases Consolidated II, 940 F.2d 832 (3d Cir.1991), cert. denied, 503 U.S. 906, 112 S.Ct. 1262, 117 L.Ed.2d 491 (1992).

11. Counsel for the forty-two plaintiffs concede that they filed suit in Mississippi to take advantage of Mississippi's six-year statute of limitations. Pennsylvania had a two-year statute. In re TMI, 67 F.3d 1103, 1105 n. 3 (3d Cir.1995), cert. denied, 516 U.S. 1154, 116 S.Ct. 1034, 134 L.Ed.2d 111 (1996).

> new complaints to be filed and which actions do not need answers filed.

Supp. App. at 78. In response to the order, counsel for plaintiffs and defendants submitted a Stipulation which provided, inter alia, that the pending TMI personal injury cases referred to as "Cases Consolidated I" and "Cases Consolidated II," together with the companion Mississippi cases, would be consolidated under a single civil action number "for administrative purposes" (emphasis added). App. Vol. I, at 440. The Stipulation required that pleadings dealing with issues common to all plaintiffs, or a legal issue potentially applicable to all plaintiffs, bear the caption "In re TMI Consolidated Proceedings" as well as the additional legend: "This document Relates to: All Plaintiffs." Id. The Stipulation further required that pleadings dealing with issues relating to one or more identified plaintiffs be captioned "In Re TMI Consolidated Proceedings" and identify lead counsel, the number of plaintiffs represented by lead counsel and the number of plaintiffs to whom the pleadings refer. Id. The Stipulation also expressly provided that

> 3. Nothing in . . . this Stipulation . . . shall be deemed to constitute or affect any waiver of claim, defense or issue, including but not limited to the statute of limitations, choice of law and bifurcation or consolidation for trial of claims, defenses, issues, parties or proceedings.

Id. The Stipulation was subsequently approved by the District Court.

Thereafter, in July of 1992, the defendants filed a motion for summary judgment directed to the forty-two plaintiffs who had sued in Mississippi state and federal courts. Defendants alleged that those claims were untimely under Section 11(b) of the Price-Anderson Amendments Act of 1988, codified at 42 U.S.C. § 2014(hh) (the choice of law provisions), which provides that "the substantive rules of decision in [any public liability action] shall be derived from the law of the State in which the nuclear incident involved occurs," and under Section 20(b) of that Act, (the effective date provision), which provides that "the amendments made by Section 11" of the Act "shall apply to nuclear incidents occurring before, on, or after the date of the enactment of this Act." 42 U.S.C. § 2014 note. The District Court ruled that the Mississippi actions were time-barred, dismissed the respective claims, and granted summary judgment in favor of the defendants because it reasoned that § 20(b), read in conjunction with § 11, compelled the retroactive application of Pennsylvania's two-year statute of limitation to the plaintiffs' claims. In re TMI Cases Consolidated II, No. 1:CV-88-1452, 1996 WL 506522, slip op. at 2-6 (M.D.Pa. Aug. 16, 1993).

On appeal, the Mississippi plaintiffs argued, inter alia, that retroactive application of the choice of law provision violated constitutional guarantees of due process. We disagreed, and held that the retroactive application of the choice of law provision was a rational exercise of Congress' legislative power. Accordingly, we affirmed the District Court's grant of summary judgment, and its dismissal of the claims of the forty-two plaintiffs. In re TMI, 89 F.3d 1106 (3d Cir.1996), cert. denied, 519 U.S. 1077, 117 S.Ct. 739, 136 L.Ed.2d 678 (1997).

The defendants then moved for summary judgment against all the TMI plaintiffs, claiming that they had not breached the duty of care owed to the plaintiffs. The District Court denied the motion. The court held that state law on that issue was preempted, and that federal law determines the standard of care. In re TMI Litigation Cases Consolidated II, 904 F.Supp. 379, 395 (M.D.Pa.1994). The court also held that federal regulations[12] set the standard of care, and that each plaintiff must prove his or her individual exposure to radiation in order to establish causation, but not to establish a breach of the duty of care. Id. at 393-394. Upon defendants' motion, the District Court certified the duty of care and causation questions for interlocutory appeal.[13] On that appeal, we held that plaintiffs must establish that (1) the defendants released radiation into the environment in excess of the levels permitted by the federal regulations in effect in 1979; (2) the plaintiffs were exposed to this radiation, although not necessarily at the levels prohibited by those regulations; (3) they have injuries; and (4) radiation was the cause of those injuries. In re TMI, 67 F.3d 1103, 1119 (3d Cir.1995),

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12. See 10 C.F.R. §§ 20.105, 20.106 (1979). These regulations were in effect at the time of the TMI accident. In re TMI, 67 F.3d 1103, 1108 n. 10 (3d Cir.1995), cert. denied, 516 U.S. 1154, 116 S.Ct. 1034, 134 L.Ed.2d 111 (1996). However, the regulations have been significantly modified since then. Id. at 1111 n. 19.

13. The District Court also certified a question concerning punitive damages. We held in a separate opinion that punitive damages are recoverable under the Price-Anderson Amendments Act of 1988 so long as the money to pay such award does not come from the United States Treasury. In re TMI, 67 F.3d 1119 (3d Cir.1995), cert. denied, 517 U.S. 1163, 116 S.Ct. 1560, 134 L.Ed.2d 660 (1996).

cert. denied, 516 U.S. 1154, 116 S.Ct. 1034, 134 L.Ed.2d 111 (1996).

After remand, the District Court conducted lengthy in limine hearings in November of 1995 and in February and March of 1996, pursuant to Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993). Those hearings all relate to plaintiffs' radiation dose and medical causation expert witnesses. In January and April of 1996, the District Court issued several opinions granting the majority of the defendants' motions in limine. See In re TMI Cases Consolidated II, 166 F.R.D. 8 (M.D.Pa.1996) (granting in part defendants' motions to exclude plaintiffs' medical causation experts); Id., 922 F.Supp. 1038 (M.D.Pa.1996) (same); Id., 922 F.Supp. 997 (M.D.Pa.1996) (granting in part defendants' motions to exclude plaintiffs' radiation dose and medical causation experts); Id., 911 F.Supp. 775 (M.D.Pa.1996) (granting in part defendants' motions to exclude plaintiffs' radiation dose experts); Id., 910 F.Supp. 200 (M.D.Pa.1996) (same). Although the District Court was convinced that the majority of the plaintiffs' expert witnesses were well-qualified, the court nonetheless "found many of their opinions to be based on methodologies that were scientifically unreliable and upon data that a reasonable expert in the field would not rely upon." In re TMI Litigation Consolidated Proceedings, 927 F.Supp. 834, 839 (M.D.Pa.1996). Accordingly, it ruled that the much of the expert testimony was inadmissible under Daubert, and its progeny. In April of 1996, the defendants filed a motion for summary judgment. They based the motion upon their contention that the District Court's Daubert rulings left the plaintiffs with no admissible evidence as to the radiation dose levels resulting from the TMI accident.

Appendix A

A subsidiary issue arose during the summary judgment proceedings as to whom the summary judgment rulings would apply. That dispute had its beginnings in June of 1993, when the District Court adopted the plaintiffs' proposed case management plan which called for an "initial mini-trial of the claims of twelve 'typical' plaintiffs," half chosen by plaintiffs and half chosen by defendants. App. at 168. Under the plaintiffs' plan (which was adopted by the District Court), discovery would proceed immediately as to all issues, including punitive damages and, upon completion of discovery, "the twelve illustrative Plaintiffs would then proceed to trial on all their claims." Id. Ultimately, ten test plaintiffs,[14] who have been diagnosed with the listed illnesses, were chosen.[15]

When the defendants filed their motion for summary judgment, they captioned it as pertaining to "All Plaintiffs" and argued that the District Court's summary judgment motion should be binding on all plaintiffs, not just the ten trial or test case plaintiffs. The District Court agreed, stating:

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14. As things developed, one of the defendants' test case selections withdrew from the test group. Consequently, the District Court permitted defendants to chose one of the parties originally selected by plaintiffs to be dismissed from the test case group. In re TMI Litigation Consolidated Proceedings, 927 F.Supp. 834, 837 n. 5 (M.D.Pa.1996). Thus, the test case group consisted of ten plaintiffs.

15. Those plaintiffs are: Paula Obercash, acute lymphocytic leukemia; Gary Villella, chronic myelogenous leukemia; Leo Beam, chronic myelogenous leukemia; Joseph Gaughan, thyroid cancer; Lori Dolan, Hurthle cell carcinoma; Jolene Peterson, thyroid adenoma; Richard Ward, osteogenic carcinoma of the right leg; Pearl Hickernell, breast cancer; Ethelda Hilt, adenocarcinoma of the ovaries; and Kenneth Putt, bladder cancer, acoustic neuroma.

> The court finds that resolution of the issue before it turns on the grounds upon which the court ultimately grants or denies summary judgment. Defendants are correct that to the extent the ruling turns on broad evidentiary issues common to all Plaintiffs, the ruling will be binding on all Plaintiffs. Likewise, Plaintiffs are correct that insofar as a ruling is based on a more narrow, Plaintiff-specific inquiry, the ruling will apply only to certain Plaintiffs. The court's reading of documents related to the June 15, 1993 order, in conjunction with subsequent case management orders and evidentiary rulings, indicates that discovery and evidentiary matters were to proceed on an "All Plaintiffs" basis. A contrary intention or result would obviate all benefits of having consolidated the many separate actions. Each Plaintiff's case depends upon expert testimony to prove both exposure and medical causation. Expert discovery is complete, and all expert reports have been filed. Thus, to the extent that the expert testimony of record fails to meet the test Plaintiffs' evidentiary burden at this state of the litigation, it will fail to meet the same burden as to every Plaintiff. It would be an exercise in futility and a waste of valuable resources to allow the many separate actions consolidated under this caption to proceed if it were clear that the cases could not withstand a motion for summary judgment. Under such circumstances, the court's summary judgment ruling will be applicable to all Plaintiffs.

927 F.Supp. at 838.

Appendix A

The District Court ruled on the merits of the summary judgment motion that the Trial Plaintiffs had failed to present either direct or indirect evidence of the doses of cancer inducing levels of radiation that they were exposed to. Id. at 870. Accordingly, the court extended its grant of summary judgment to all of the plaintiffs' cases.

> Because the court finds the quantum of evidence on the issue of dose to be insufficient, and because no Plaintiff will be able to state a prima facie case without adequate dose evidence, the instant ruling is binding on all Plaintiffs.

Id. at 838. Accordingly, the court granted summary judgment against all of the plaintiffs, both trial and nontrial.

These appeals followed.

Appeal Number 96-7623 is the appeal of the ten Trial Plaintiffs. They argue that the District Court improperly excluded their proffered expert witnesses' testimony on dose exposure, thereby erroneously subjecting them to summary judgment. They do not argue that summary judgment was improper given the District Court's Daubert rulings. Thus, if we determine that the District Court's exclusion of their dose exposure testimony was proper, we must affirm the summary judgment for the defendants against the trial plaintiffs. Consequently, the primary issue for our determination in case number 96-7623 is the propriety of the District Court's exclusion of testimony of the dose exposure experts. If, however, we decide that the court improperly excluded some or all of that evidence, we must

then decide whether the evidence that was admissible is sufficient to create a genuine issue of material fact.

Appeal Number 96-7624 is the appeal of all of the TMI personal injury plaintiffs except the ten Trial Plaintiffs. Appellants there argue that the District Court improperly extended its Trial Plaintiffs' summary judgment decision to them. Appeal Number 96-7625 is the appeal of sanctioned counsel for the majority of the plaintiffs. Counsel argue that the District Court's imposition of monetary sanctions against them for discovery violations was improper. Each appeal is considered separately.

It is both impractical and unwise to begin our analysis of the Daubert challenge to the scientific testimony without first providing a brief discussion of the fundamental principles of nuclear physics, nuclear engineering, the TMI-2 accident, ionizing radiation, and the health effects of ionizing radiation on the human body. These scientific principles are at the center of the damage that plaintiffs claim they suffered as a result of the TMI accident and the District Court's Daubert rulings. Total immersion in the complexities of these disciplines is neither required, nor possible. Accordingly, we offer the following overview of the controlling principles with an awareness that doing so stretches the boundaries of our institutional competence, and with a recognition of our need to borrow heavily from others in academic disciplines far from the familiar confines of the law.

Appendix A

III. SCIENTIFIC BACKGROUND

A. Overview of Relevant Principles of Nuclear Physics.

1. Atomic and Nuclear Structure.

Plaintiffs alleged that the accident at TMI resulted in a release of radiation into the atmosphere that caused changes to the atomic structure of their chromosomes and resulted in the formation of neoplasms. Their allegations thus implicate the structure of the atom — the basic building block of matter — and the physics of orbiting electrons.[16]

The atom consists of a small but massive central nucleus surrounded by one or more orbital electrons. JOHN R. LAMARSH, INTRODUCTION TO NUCLEAR ENGINEERING 8 (2d ed.1983). Orbiting electrons are negatively charged, much smaller in mass than the neutron, and their distances from the nucleus are much larger than the radius of the nucleus. DAVID BODANSKY, NUCLEAR ENERGY: PRINCIPLES, PRACTICES AND PROSPECTS 346 (1996). The average distance from the nucleus to the place where the outermost electron is found provides an approximate measure of atomic size. This distance is approximately the same for all atoms, except a few of the lightest atoms, and is about 2 x 10-8 centimeters.[17] LAMARSH, at 11.

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16. As we discuss below, radiation has the potential to fatally interfere with one of more orbiting electrons.

17. It is difficult to define the exact size of an atom because the orbiting electrons may at times move very far from the nucleus but at other times pass close to it. LAMARSH, at 7.

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The nucleus has two constituent parts of approximately equal mass — the neutron and the proton.[18] BODANSKY, at 346. Each is much more massive than the electron. LAMARSH, at 6-7. Together, they are called nucleons. BODANSKY, at 346. The neutron and proton differ in that the neutron is neutral while the proton has a positive charge equal in magnitude to the negative charge of the electron. Id. An atom is neutral or "un-ionized" when the number of positively charged protons equals the number of negatively charged electrons. D.J. BENNET, ELEMENTS OF NUCLEAR POWER 1 (2d ed.1981).[19] "Nuclides" are very

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18. At one time, it was believed that neutrons and protons were the fundamental particles of nature. However, it is now understood that they are not the fundamental particles of nature, but themselves are composed of more elementary particles called quarks. BODANSKY, at 346. While knowledge of the existence of quarks and other elementary particles is crucial to an understanding of the origins of the universe and of the ultimate structure of matter, their existence can be ignored in a discussion of nuclear reactors, radioactivity and nuclear fission. Id.

19. Forces exist in an atom that are critical to atomic structure. "Coulomb repulsion" is an electrostatic force, governed by Coulomb's law, which exists between objects that carry the same electrical charge. BODANSKY, at 349 n. 3. The repulsion exists not only on a microscopic scale, but also on an atomic scale, BENNET, at 8, and, therefore, it exists between the protons in the nucleus because they are positively charged. Consequently, Coulomb repulsion tends to disrupt (or burst) the nucleus. Id. The fact that the nucleus of a stable atom is not disrupted indicates that there is another force which overrides Coulomb repulsion, and holds the nucleus together. Id. This force, known as the "strong" or "nuclear force", exists between particles that are incredibly close to each

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important to our discussion. They are differing "species" of atoms whose nuclei contain particular numbers of protons

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other, within about 3 x 10-15 meters. The strong force acts with approximately equal strength between two protons, two neutrons or a proton and a neutron and binds the nucleus together, so long as the separation between the particles is less than 3 x 10-15 meter space in which the strong force operates to cancel Coulomb repulsive. Id.

Coulomb repulsion is not the only electrostatic force defining atomic structure. "Coulomb attraction" exists between oppositely charged particles and this attractive force, operating between the electrically positive protons and the electrically negative electrons, causes the electron to orbit around the nucleus of the atom. RONALD ALLEN KNIEF, NUCLEAR ENGINEERING: THEORY AND TECHNOLOGY OF COMMERCIAL NUCLEAR POWER 29 (2d ed.1992).

The chemical properties of an element are determined by the number of electrons surrounding the nucleus in an unionized atom, and the number of electrons orbiting the atom is equal to the number of protons in the nucleus. BODANSKY, at 346. That is, a neutral atom has the same number of protons and electrons, and the number of protons in the nucleus, (given the symbol "Z"), is the atomic number of a particular element and identifies it. KNIEF, at 29. Electrons are responsible for the chemical behavior of the atoms and they identify the chemical elements. LAMARSH, at 8. Consequently, each element is identified in terms of its atomic number, Z. BODANSKY, at 346.

The number of neutrons in the nucleus is known as the "neutron number" and is denoted by the letter "N". LAMARSH, at 8. The sum of the number of neutrons and protons, i.e., nucleons, in the nucleus is called the atomic mass number or "mass number", A. Thus, the formula: A = Z + N. Id.

and neutrons. LAMARSH, at 8. A nuclide is given the shorthand notation A subZ X, where X is the symbol for the chemical element, Z is the atomic number and A is the atomic mass number. KNIEF, at 29. In general practice, however, the subscript Z is omitted because once the element, X, is given, so is the atomic number, Z. BODANSKY, at 346. Nuclides whose nuclei contain the same number of protons, i.e., the same Z, but different numbers of neutrons, i.e., different N and therefore a different mass number, A, are called isotopes of the element. BENNET, at 2. All elements have a number of isotopes, Id., and they are virtually identical in their chemical properties to the elements they are isotopes of. BODANSKY, at 346. However, the masses and other characteristics of their nuclei are different. BENNET, at 2. An isotope of an element is given the same shorthand notation as the nuclide. For example, naturally occurring oxygen, whose chemical symbol is "O", consists of three isotopes, 16O, 17O, and 18O. Id. Each has 8 protons and electrons, i.e., the same atomic number, Z, but they have 8, 9 and 10 neutrons respectively, i.e., different N (N = A - Z). The nuclei of a given element can have the same mass number, A, but have a different atomic number, Z, in which case it is called an isobar. BODANSKY, at 346.

Though counterintuitive in the extreme, it is nevertheless a fact of atomic structure that the mass of an atom is less than the sum of the masses of its constituent parts. BENNET, at 4; BODANSKY, at 350; KNIEF, at 29; LAMARSH, at 28. The difference between the mass of the assembled atom and the sum of the mass of the component atomic parts is known as the "mass defect". KNIEF, at 29. However, mass is not really lost in the assembly of an atom from its

component parts. Rather, the mass defect is converted into energy when the nucleus is formed. Id. The conversion is explained by the "principle of the equivalence of mass and energy in which Einstein stated that mass and energy are different forms of the same fundamental quantity."[20] BENNET, at 4. Therefore, in any reaction where there is a reduction in mass, the decrease is accompanied by a release of energy. Id. The energy associated with the mass defect is called "binding energy" and it represents the total energy that would be required to disassemble a nucleus into its constituent neutrons and protons. BODANSKY, at 350. Binding energy increases in a nucleus as the number of particles in the nucleus increase. In other words, binding energy increases with a corresponding increase in atomic mass number. LAMARSH, at 28. However, the rate of increase is not uniform. KNIEF, at 30.

The amount of binding energy in a nucleon is important when determining possible sources of nuclear energy. LAMARSH, at 28. A nuclei is stable or tightly bound when the binding energy per nucleon is high. Accordingly, a relatively large amount of energy must be supplied to break the stable nuclei apart. Id. When a tightly bound nucleus is broken apart and two nuclei of intermediate mass are formed, a relatively large amount of energy is released. BENNET, at 7. In contrast, nuclei with low binding energy per nucleon are easily broken apart, and less energy is released. LAMARSH, at 29.

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20. The equivalence between mass and energy is expressed in Einstein's famous equation, E = mc2, where E is energy, m is mass and c is the speed of light. KNIEF, at 28.

Appendix A

The now familiar term, "nuclear fission" refers to the process of causing a tightly bound nucleus to split into two nuclei of intermediate mass. Id. The process proceeds in the direction of increased binding energy per nucleon. BENNET, at 7. That is, the nuclei of intermediate mass created by the fission process have greater binding energy than the original nucleus. LAMARSH, at 30. When the nuclei of intermediate mass have greater binding energy than the original nucleus, energy is released during the formation of the final nuclei. BODANSKY, at 351. This energy that is released as a result of the fission process is the source of energy in a nuclear reactor. LAMARSH, at 30. It is what we commonly refer to as "nuclear energy".

Atoms can exist only in certain states or configurations, with each state having its own specific energy. BODANSKY, at 351. The different energy states correspond to different electron orbits of different radii, LAMARSH, at 15, each with an energy level equal to the sum of the kinetic and potential energies of the electron in its orbit. BODANSKY, at 351. The lowest state of energy is called the "ground state" and it is the state in which the atom is normally found. LAMARSH, at 15. However, an electron can, as a result of a nuclear reaction, jump from its normal orbit to an orbit that is farther from the nucleus. An increase in energy corresponds to this "jump", and when an atom has more energy than its ground state it is said to be in an "excited state". BENNET, at 8. An atom can have a number of excited states which correspond to the number of jumps the electron has made. Id. The highest energy state occurs when the electron is completely removed from the atom. LAMARSH,

at 15. The complete removal of an electron from an atom is called "ionization" and the resulting atom is said to be "ionized". Id.

The nucleons in the nuclei also move in orbits; however, the orbits of nucleons are not as well defined, and are not as well understood, as the orbits of electrons. LAMARSH, at 16. Like atoms, nuclei normally exist in the ground state. BENNET, at 8; BODANSKY, at 352. However, nuclei can reach excited states just as atoms can. BENNET, at 8; BODANSKY, at 352. The process is more complicated in nuclei than in atoms because excitation of nuclei can result in several nucleons being raised to excited levels simultaneously. BENNET, at 8. Although it is not yet possible to account theoretically for the exact energy levels of nuclei, as it is possible to do so for atoms. BODANSKY, at 352. It is generally true that the energies of the excited states and the energies between states are much greater for nuclei than for atoms. LAMARSH, at 16. The greater energy results from the greater forces acting between nucleons. These forces are much stronger than the forces acting between electrons and the nucleus. Id.

With a few exceptions, excited states in either atoms or nuclei exist for only a very short time, about 10-14 seconds. BENNET, at 9. Excess energy is quickly emitted and the system, either atomic or nuclear, decays to states of lower energy until it ultimately returns to its ground state. LAMARSH, at 15. The process of going from one state to another is called a "transition". Id. The energy lost in a transition is usually carried off by electromagnetic

radiation,[21] BENNET, at 9; BODANSKY, at 352, with the lost energy equal to the difference in the energies of the two states.[22] LAMARSH, at 15.

2. Radioactivity.

As suggested by our discussion thus far, nuclei are either stable or unstable. For all practical purposes, stable nuclei remain unchanged forever. Unstable nuclei decay spontaneously into lighter nuclei pursuant to a time scale

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21. Sometimes, however, the energy can be transferred to an electron through a process known as "internal conversion" which leaves the nuclide unchanged. At other times, an excited state can decay be emitting a particle, such as a beta (<<beta>>) particle or a neutron, thus changing the atomic number of the nuclide. BODANSKY, at 352 n. 8.

22. The electromagnetic radiation corresponding to an atomic or nuclear transition is contained in a single discrete packet called a "photon". BODANSKY, at 352. At one time, light and other forms of electromagnetic radiation were described as waves. However, it is now known that electromagnetic radiation behaves at times like a particle. Id. Thus, a photon is both wave-like and particle-like in character. LAMARSH, at 7. Visible light is associated with transitions involving the outer electrons of atoms. X-rays correspond to transitions involving the inner electrons of atoms. Gamma (<<gamma>>) rays correspond to transitions from nuclei. However, all are photons and there is no difference among them other than their energy, with visible light having the lowest energy and gamma (<<gamma>>) rays having the highest energy. In fact, there is really no need to distinguish between photons from atomic transitions, i.e., x rays, and photons from nuclear transitions, i.e., <<gamma>> rays. The names date from the time of their discovery and are probably kept only as a reminder of their origin. BODANSKY, at 352.

that is unique for every element (the "half-life").[23] The half-life for a given element is defined as the time required for one-half of a given sample of the element to "decay." If the half-life is greater than some undefined fraction of a second, the process of decay is called "radioactivity." Half-lives vary from less than a second to many billions of years. BODANSKY, at 353. Radioactivity is then, the process by which unstable nuclei seek stability. KNIEF, at 31. Frequently, the original unstable nucleus, called the "parent nucleus", decays to another radioactive nucleus, called the "daughter nucleus." LAMARSH, at 19. There may be more than one radioactive daughter nuclei produced until stability is reached. BENNET, at 11. This process of the creation and subsequent decay of several daughter nuclei is referred to as a "decay chain". LAMARSH, at 19.[24]

The exact time at which any single nucleus will decay cannot be determined. KNIEF, at 34. However, the average behavior of a very large sample of radioactive material can be described statistically. BENNET, at 15. For a given nuclide, there is an average time, called the "decay constant", which characterizes its rate of decay. Id. The decay constant is defined as the probability per unit of time that a decay

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23. Sometimes designated as: "T sub1/2".

24. For example, there are three natural radioactive decay chains whose parent isotopes have very long-half lives. The three are uranium 238 (T sub1/2 = 4.51 x 109 years), uranium 235 (T sub1/2 = 7.1 46 x 108 years), and thorium 232 (T sub1/2 = 1.41 x 1010 years), and their decay chains contain many radioactive daughter isotopes leading eventually in each case to a stable isotope of lead. BENNET, at 18-19.

will occur. KNIEF, at 34. The amount of radioactivity present during a decay is referred to as "activity". FRED A. METTLER, JR., M.D., AND ARTHUR C. UPTON, M.D., MEDICAL EFFECTS OF IONIZING RADIATION 7 (2d ed.1995) (hereinafter "MEDICAL EFFECTS"). The activity of a given sample is the average number of disintegrations per unit of time. For a large sample, the activity is the product of the decay constant and the number of atoms present. Id. The traditional unit for measuring radioactivity is the curie (Ci), which is defined as 3.7 x 1010 disintegrations per second.[25]

A radioactive nuclide is called a "radionuclide." KNIEF, at 32. During the process of radioactive decay, the nucleus spontaneously emits an alpha (<<alpha>>) particle or a beta (<<beta>>) particle. BODANSKY, at 354. The emission of these particles is often accompanied by the emission of one or more gamma (<<gamma>>) rays. Id. An alpha (<<alpha>>) particle is a highly stable nucleus of the isotope helium 4(4He), consisting of two protons and two neutrons. LAMARSH, at 20.[26] Alpha (<<alpha>>) particles have a double positive charge and are emitted in a discrete energy spectrum. Id. They have a low level of energy and, therefore, are only capable of penetrating matter a small distance.[27]

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25. The curie, is however, being superseded by a new measuring unit called the "Becquerel" (Bq), which is defined as one disintegration per second. BENNET, at 16.

26. Thus, the emission of an alpha (<<alpha>>) particle reduces the atomic number (Z) of the unstable nuclei by two and the mass number (A) by four. LAMARSH, at 20.

27. The most energetic of the alpha (<<alpha>>) particles are stopped after passing through less than 10 centimeters of air or about 0.1 millimeters of a material such as water. BODANSKY, at 355.

Appendix A

Decay by alpha particle emission is rather rare for nuclides lighter than lead (Pb) which has an atomic number (Z) of 82. BODANSKY, at 355. However, many of the naturally occurring radioactive elements with atomic numbers between 84 (polonium) and 92 (uranium), i.e., the heavier elements, decay by alpha particle emission. BENNET, at 13. When these elements decay, the daughter product is closer to the stability region than the parent. Id. In addition, the daughter nucleus of these heavier elements is frequently formed at an excited state of energy so that the excited nucleus immediately decays further to its ground state by the emission of gamma (<<gamma>>) radiation. Id. Thus, the decay of a heavy radioactive isotope by alpha particle emission also produces gamma (<<gamma>>) radiation. Id.

A beta (<<beta>>) particle is an electron of nuclear, not orbital, origin, KNIEF, at 33, but it is identical to the electrons that orbit the nucleus. BODANSKY, at 355. Because it is an electron, it has much less mass than an alpha particle. Id. A neutron that is bound into the nucleus is not stable. LAMARSH, at 7. During decay, a neutron in the nucleus is transformed into a proton and an electron and it is this electron which is emitted as a beta (<<beta>>) particle. Id.; BENNET, at 13.

Because beta (<<beta>>) particle decay has the effect of transforming one of the neutrons into a proton, the resulting daughter nucleus has the same mass number (A) as the parent, but its atomic number (Z) is greater by one. Id. Moreover, the daughter nucleus may be formed in an excited state, and decay to its ground state by the emission of gamma (<<gamma>>) radiation. Id.

Appendix A

In most cases, beta particles are negatively charged and are more properly designated as <<beta>>- particles. Positive electrons, called "positrons" or <<beta>>+ particles, are emitted from artificial radionuclides that are produced when positive particles, such as protons or alpha (<<alpha>>) particles, combine with a nucleus to form an unstable proton-rich nucleus. BODANSKY, at 355. These beta particles are very rare in naturally existing material. Id.

Beta (<<beta>>) particles do not all have the same energy. BENNET, at 13. The spectrum of the energy of these particles, ranges from zero to a fixed maximum or "endpoint energy." BODANSKY, at 357.[28] However, the average energy of beta particles is about one-third, BENNET, at 13, to one- half, BODANSKY, at 357, the endpoint energy. The remaining two-thirds to one-half of maximum possible beta (<<beta>>) particle energy is shared with another particle called the neutrino.[29] BENNET, at 13; BODANSKY, at 357. A neutrino is one of nature's more curious phenomena. It has no charge, and virtually no mass. KNIEF, at 33. It was once thought to have no mass; however, it is now believed that the neutrino may have mass, albeit very small mass.

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28. The endpoint energy corresponds to the mass difference between the parent atom and the residual product, as the principle of conservation of mass plus energy demands. BODANSKY, at 357.

29. Strictly speaking, the neutrino emitted in <<beta>>- decay is an anti-neutrino, while the neutrino itself is emitted in <<beta>>+ decay. When the distinction between them is not important, they are both referred to as neutrinos. Again, strictly speaking, the <<beta>>- neutrino are called particles, while the <<beta>>+ and anti-neutrino are called anti-particles. BODANSKY, at 357.

BODANSKY, at 357; Malcolm W. Browne, Los Alamos Experiment Shows Neutrino Probably Has Mass, N.Y. Times, May 7, 1996.

Beta (<<beta>>) particle decay usually occurs when a nuclide has an excess of neutrons. BENNET, at 13; BODANSKY, at 358. A beta particle has greater penetrating ability than an alpha particle, BENNET at 21, with average penetration distances ranging from 0.1 to 1 g/cm2, increasing with increasing energy. BODANSKY, at 355. A neutrino, however, has great penetrating power and can pass through very large amounts of material without stopping. Id. at 358.

As discussed earlier, gamma (<<gamma>>) radiation is electromagnetic radiation emitted in the form of photons by nuclei in excited states of energy. Except as noted below, gamma (<<gamma>>) emission is not a primary process of radioactive decay. Instead, it follows alpha (<<alpha>>) particle or beta (<<beta>>) particle emission. Gamma (<<gamma>>) rays do not have mass or charge, and they are therefore capable of much greater penetration of matter than alpha (<<alpha>>) or beta (<<beta>>) particles.[30] BODANSKY, at 355.

Earlier, we noted that excited states in nuclei exist for a very short time (about 10-14 seconds). Consequently, half-lives for gamma (<<gamma>>) ray emission are typically very short. BODANSKY, at 359. However, some nuclei have long-lived excited states, called "isomeric states",

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30. Gamma rays can penetrate to distances ranging from 5 to 20 g/cm2. BODANSKY, at 355.

with half-lives ranging from a fraction of a second to many years. Id. In fact, in some cases, the excited state is so long that the nuclei appear semi-stable. LAMARSH, at 21. The decay to a lower state of energy by gamma (<<gamma>>) ray emission in a nuclei in an isomeric state is called an "isomeric transition". Id. In such a case, gamma (<<gamma>>) ray emission appears to be the primary radioactive process of, rather than incident to, alpha (<<alpha>>) or beta (<<beta>>) particle emission. Gamma ray emission can, however, ultimately be traced back to either initiating process.[31] BODANSKY, at 359.

3. Ionizing Radiation.

The legal dispute before us is rooted in the damage that purportedly resulted from defendants' release of ionizing radiation into the atmosphere. There are a number of ways in which an ion, or charged particle, can interact with an atom. First, because it is charged, the particle exerts an electrostatic or "Coulomb force" on the atom's electrons. The exertion of Coulomb force has various effects upon an atom. One or more of the electrons may move to an outer orbit, leaving the atom in an excited state of energy or an electron may be entirely ejected from the atom. The latter event results in the formation of an ionized atom. LAMARSH, at 88. When an atom is ionized, it is split into

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31. There is an alternative to gamma (<<gamma>>) ray emission called "internal conversion", in which the excitation energy is transferred to one of the inner electrons of the atom. Typically, gamma (<<gamma>>) ray radiation and internal conversion are competing processes by which excited nuclei reach the ground state. BODANSKY, at 359.

an ion pair. The negatively charged electron of this pair is the negative ion, and the atom minus its negatively charged electron is the positive ion. BENNET, at 20. This process of ionization produces ionizing radiation.[32] MEDICAL EFFECTS, at 1.

The second possible result is that the charged particle may penetrate the cloud of orbiting electrons and collide with the nucleus. After collision, the charged particle is scattered from the nucleus, and, since momentum and energy are conserved in the collision, the nucleus recoils. If the charged particle has sufficient mass and energy, the recoiling nucleus may be ejected from its own electron cloud and itself become a charged particle. LAMARSH, at 88. In addition, under certain circumstances, the charged particle, particularly if it is an alpha (<<alpha>>) particle, may undergo a nuclear reaction when it collides with the nucleus. The charged particle may also be accelerated by the electrostatic or Coulomb field of the electrons or the nucleus and a photon may be emitted.[33] Id.

Whichever of these alternative results occurs, a charged particle is created. When a charged particle passes through matter, it excites and ionizes atoms in its path. Id. However, these charged particles lose energy by virtue of the

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32. Ionizing radiation is only a small part of the electromagnetic spectrum, which includes radio waves, radar, microwaves, ultraviolet radiation and electric power. MEDICAL EFFECTS, at 1-2.

33. This latter kind of radiation that is emitted when a charged particle becomes accelerated, is called "bremsstrahlung". Id. LAMARSH, at 88.

electrostatic forces created by their interaction with the atoms that comprise the matter through which the charged particles pass. KNIEF, at 70. The electrostatic forces acting upon the charged particles are proportional to the product of the charges and inversely proportional to the square of the distance between them. Thus, the force decreases rapidly with distance, but becomes negligible only at very large distances. Id. At any given interval, a charged particle experiences forces from a very large number of electrons. The resulting energy losses are well defined for each charged particle and each material medium. Id. The net microscopic effect of charged-particle interactions is characterized by range and linear energy transfer ("LET"). Id. Range is the average distance traveled by a charged particle before it completely stops. The LET is the amount of energy deposited per unit of particle track, which gives rise to the excitation and ionization. LAMARSH, at 89. The range and the LET of a specific radiation contribute to the effect they have on a material, with the range determining the distance of penetration and the LET determining the distribution of energy deposited along the path. KNIEF, at 70.

The LET is of particular significance to an inquiry into the biological effects of radiation. Those effects depend upon the extent to which energy is deposited by radiation as excitation and ionization within a given biological system. LAMARSH, at 89. The LET increases with the mass and charge of a moving particle. Id. Consequently, heavy charged particles, such as alpha (a) particles, are referred to as high LET radiation. Id.

Appendix A

Charged particles are referred to as "directly ionizing radiation" because they are directly responsible for producing ionization. LAMARSH, at 88; BENNET, at 20; BODANSKY, at 354. Uncharged particles, such as gamma (<<gamma>>) rays, lead to excitation and ionization only after interacting with matter and producing a charged particle. Accordingly, uncharged particles are referred to as "indirectly ionizing radiation." LAMARSH, at 88.

While gamma (<<gamma>>) rays can interact with matter in a variety of ways, there are, for purposes of our analysis, three important types of interaction between gamma (<<gamma>>) radiation and matter — the "photoelectric effect", "pair production" and "Compton scattering." BENNET, at 21. Because very short-range forces govern electromagnetic mechanisms, a gamma (<<gamma>>) ray must essentially "hit" an electron for an interaction to occur. KNIEF, at 71. In the photoelectric effect, which is the most important process at low gamma (<<gamma>>) ray energies, BENNET, at 199, the gamma (<<gamma>>) ray interacts with the entire atom, the gamma (<<gamma>>) ray disappears and one of the atomic electrons is ejected from the atom. LAMARSH, at 79. As a result, the energy of the gamma (<<gamma>>) ray or photon is converted completely to kinetic energy of an orbital electron. KNIEF, at 71. If the gamma (<<gamma>>) ray ejects an inner electron, the resulting hole in the electron cloud is filled by one of the outer electrons. LAMARSH, at 16, 79. This transition is accompanied either by the emission of an X-ray or by the ejection of another electron.

Appendix A

Pair production occurs only for high-energy gamma (<<gamma>>) rays and only in the vicinity of a heavy nucleus. Id. at 80; BENNET, at 21. The gamma (<<gamma>>) ray is annihilated; and an electron pair — a positron and a negatron — is created. LAMARSH, at 80. When this occurs the energy of the gamma (<<gamma>>) ray converted to mass, and kinetic energy of the electron pair. KNIEF, at 71. Once they are formed, the positron and negatron move around and ultimately lose energy as a result of collisions with atoms in the surrounding matter. LAMARSH, at 80. After the positron has slowed to very low energies, it combines with a negatron, the two disappear and two photons are produced. LAMARSH, at 80-81. The photons that are produced are called "annihilation radiation." Id. at 7.

Compton scattering occurs when the gamma (<<gamma>>) ray strikes an electron and is scattered. The electron that is struck in this process recoils and acquires some of the kinetic energy of the gamma (<<gamma>>) ray, Id. at 81, thus reducing the energy level of the reaction. KNIEF, at 71. Since the gamma (<<gamma>>) ray does not disappear as it does during the photoelectric effect, and is not annihilated as it is in pair production, the Compton-scattered gamma (<<gamma>>) ray is free to interact again. LAMARSH, at 82.

Although uncharged particles cause indirect ionizing radiation, it is nonetheless possible to refer to the LET of uncharged particles. However, because they have a relatively low rate of energy loss when compared to the rate of energy loss of charged particles, gamma rays (<<gamma>>) are

referred to as "low LET radiation." LAMARSH, at 89. The distinction between high LET radiation and low LET radiation has important biological consequences. Id. Given the same dose of radiation, biological damage from high LET radiation is much greater than damage from low LET radiation. Id. at 402.

4. Radiation Quantities and Units.

Radiation can be measured by counting the number of ionized particles it produces as it passes through air. INTERNATIONAL ADVISORY COMMITTEE, THE INTERNATIONAL CHERNOBYL PROJECT, TECHNICAL REPORT 20 (1991) (hereinafter "CHERNOBYL"). Originally, the amount of radiation exposure for X- and gamma (<<gamma>>) radiations was measured in units of the roentgen (R), KNIEF, at 72, which is defined as the number of electrical charges produced in a unit mass of air. CHERNOBYL, at 20.[34] Alternatively, a roentgen can be defined in terms of the amount of energy released in the production of ions with a total charge of one electrostatic unit of either sign. BENNET, at 197.[35] Thus,

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34. One roentgen is that quantity of X or gamma (<<gamma>>) radiation which produces a total charge of one electrostatic unit of either sign in one cubic centimeter of air at 1 atmosphere at 0 <<degrees>> Celsius. LAMARSH, at 400.

35. Under this definition, a roentgen is equivalent to depositing about 88 "ergs" in 1 gram of air. KNIEF, at 73. An "erg" is a unit of energy and one roentgen under the alternative energy description is energy sufficient to move the point of a sharpened pencil about 1.5 millimeters across a piece of paper. Id.

the roentgen is a unit of exposure in air and not a unit of radiation dose to body tissue. Moreover, it is not applicable to higher energy X-rays or to particulate radiations. MEDICAL EFFECTS, at 8. Consequently, the roentgen is not very useful for comparing the effects of various radiations on biological systems, particularly the human body. KNIEF, at 73.

When radiation penetrates material, its energy is absorbed and released by the constituent atoms of the material that is penetrated. CHERNOBYL, at 20. The absorbed energy per unit mass of material is termed the "absorbed dose." Id.[36] Two units are used to measure absorbed dose of any type of radiation. The original unit of absorbed dose is the "rad" (radiation absorbed dose) and is defined as 100 ergs of energy per gram of material. LAMARSH, at 401. The new unit of absorbed dose under the Systems International d'Unites ("SI")[37] is the gray ("Gy"),

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36. Heavy, highly charged particles, such as alpha (<<alpha>>) particles, lose energy rapidly over distance and, therefore, do not penetrate matter deeply. For example, alpha (<<alpha>>) particles do not penetrate the layer of dead cells on the surface of the skin. CHERNOBYL, at 19. Beta (<<beta>>) particles, because of their smaller charge and much smaller mass, are much more penetrating, BENNET at 20, and may penetrate up to several centimeters into the body. CHERNOBYL, at 19. X and gamma (<<gamma>>) rays have much greater penetrating power than either alpha (<<alpha>>) or beta (<<beta>>) particles, BENNET, at 20, and they are therefore used for medical diagnostic purposes. CHERNOBYL, at 19.

37. The SI is a modernized metric system which is becoming the standard for expressing scientific and technical data. However, much scientific and technical literature still contains the older, more customary units. KNIEF, at 671.

which is defined as one joule of energy absorbed per kilogram of matter. CHERNOBYL, at 20. Because a rad and a gray are defined in terms of energy, it is possible to equate rads with grays, with one gray being equivalent to 100 rads (1Gy = 100 rads), or one rad equivalent to 10 milligrays (1 rad = 10 mGy).[38] MEDICAL EFFECTS, at 8.

However, the absorbed dose is not the only factor to be considered in estimating radiation effects on the human body. The effects also depend on the LET of the radiation. KNIEF, at 73; LAMARSH, at 402. Even when the amounts of energy absorbed are the same, alpha (<<alpha>>) particles are more damaging to human tissue than gamma (<<gamma>>) radiation because of the higher LET of alpha (<<alpha>>) radiation. BENNET, at 198. The fact that different types of radiation have different biological effects for the same absorbed dose is described in terms of the relative biological effectiveness ("RBE") of the radiation. LAMARSH, at 402. The RBE depends on the dose, the dose rate, the physiological condition of the subject, and various other factors. The RBE is determined through experimentation. KNIEF, at 73; LAMARSH, at 403. Accordingly, there is no one RBE for a given type of radiation, and the unit is used almost exclusively in radiobiology. LAMARSH, at 403.

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38. There is another type of unit which is sometimes used for very high energy radiation and for particulate radiation. That unit is the "kerma" (kinetic energy released in matter) and it is used because it includes not only the energy deposited in the local area but also the additional energy deposited as a result of bremsstrahlung. For most purposes, the rad and the kerma are interchangeable. A major exception is the calculation of doses for atomic bomb survivors. There, the kerma was higher than the rad. MEDICAL EFFECTS, at 8.

Appendix A

RBE is, however, used to approximate the quality factor ("Q") of radiation, which is usually the upper limit of RBE for a specific type of radiation. Id.; KNIEF, at 73. For example, X-rays and gamma (<<gamma>>) rays have a Q of 1, beta (<<beta>>) particles have a Q of 1 to 1.7, depending on their energy, and alpha (<<alpha>>) particles have a Q of 20. CHERNOBYL, at 20; KNIEF, at 74. To estimate the effect of a given type of radiation on body tissue, it is necessary to determine the dose equivalent. The dose equivalent is arrived at by multiplying the absorbed dose by the quality factor of the radiation. The original unit of dose equivalence is the "rem" (roentgen equivalent man) and is the product of the absorbed dose in rad and the Q of the particular radiation. LAMARSH, at 404. Thus, if the radiation is gamma (<<gamma>>) radiation, then an absorbed dose of 1 rad produces a dose equivalent of 1 rem, and if the radiation is alpha (<<alpha>>) particle radiation, then an absorbed dose of 1 rad produces a dose equivalent of 20 rem. The new SI unit of dose equivalence is the sievert (Sv) and is the product of the absorbed dose in gray (Gy) and the Q of the radiation. BENNET, at 198. Since one gray equals 100 rads (1 Gy = 100 rads), then one sievert equals 100 rem (1 Sv = 100 rem), LAMARSH, at 404, or one rem equals 10 millisieverts (1 rem = 10 mSv). MEDICAL EFFECTS, at 8.

The effect of a given dose equivalent varies depending on the tissue or organ exposed to the radiation. CHERNOBYL, at 20. For example, a given dose of radiation to the hand may have a different and far less serious effect than the same dose delivered to a blood-forming organ. Similarly, the biological effect of a given dose of radiation

to a blood-forming organ will be different from a like exposure to reproductive tissue. LAMARSH, at 404. However, equal dose equivalents from different sources of radiation, if delivered to the same point in the body, should have approximately the same biological effect. Id. at 403.

The "effective dose" (E), is a unit that is derived from the equivalent dose in an attempt to indicate the combined effect of different doses of radiation upon several different tissues or body parts. CHERNOBYL, at 20. The effective dose is the product of the equivalent dose in a tissue or organ (T) multiplied by a factor called the "tissue weighing factor" (WT), which represents the contribution of that tissue or organ to the total harm resulting from uniform radiation exposure to the whole body. Id.[39]

Each of the preceding units, (i.e., absorbed dose, equivalent dose and effective dose) relate to the radiation exposure of an individual. There are, however, units of exposure for groups of people. They are arrived at by multiplying the average dose to the exposed group by the number of people in the group. CHERNOBYL, at 20-21. The units are the "collective equivalent dose," which relates to a specified tissue or organ, and the "collective effective dose," which relates to all the people exposed to the radiation.

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39. By way of illustration, the tissue weighing factor for the gonads is 0.20, the tissue weighing factor for red bone marrow is 0.12, and the tissue weighing factor for the skin and bone surface is 0.01. CHERNOBYL, at 20. The effective dose is the weighted sum of the equivalent doses in all the tissues and organs of the body and is a measure of the total risk from any combination of radiations affecting any organs of the body. Id.

Id. Both units are expressed in terms of man-rems or man-sieverts. LAMARSH, at 405, and they represent the total consequences of the exposure of a population or group. CHERNOBYL, at 21.

5. Health Effects of Ionizing Radiation.

Soon after the discovery of x-rays and natural radioactivity, clinical evidence suggested that ionizing radiation is harmful to human tissue. ANNALS OF THE INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, ICRP PUBLICATION 60, 1990 RECOMMENDATIONS OF THE INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION 94 (1990) (hereinafter "ICRP 60"). The initial evidence was mainly noted from the effect of ionizing radiation on human skin.[40] Id. at 92. Later, scientists realized that exposing germinal tissue in plants and animals to ionizing radiation produced effects not only in the plants and animals that were actually exposed, but also in subsequent generations of the exposed plants and animals. Id. Scientific studies and investigations over the last century, have now given us a wealth of information about the effects of radiation on humans.[41] These studies include extensive in vitro and in vivo animal experiments, Id., the comprehensive

40. Ionizing radiation causes nonmalignant skin damage called erythema or reddening of the skin. LAMARSH, at 409.

41. One commentator has noted that "more than 80,000 studies have been reported in the scientific literature, indicating that radiation effects have been studied far more thoroughly than other environmental impacts." KNIEF, at 77.

epidemiological studies of the survivors of the atomic bombings of Hiroshima and Nagasaki, studies of x-rayed tuberculosis patients; and studies of people exposed to ionizing radiation during treatment for ankylosing spondylitis, cervical cancer and tinea capitis. NATIONAL RESEARCH COUNCIL, COMMITTEE ON THE BIOLOGICAL EFFECTS OF IONIZING RADIATIONS, HEALTH EFFECTS OF EXPOSURE TO LOW LEVELS OF IONIZING RADIATION 2(1990) (hereinafter "BEIR V"). These studies have allowed science to "narrow the range of uncertainties in human radiobiology." CHERNOBYL, at 37.

As noted earlier, an atom is ionized when an electron is ejected from its orbit and expelled from the atom. As ionizing radiation passes through human tissue, it can transfer its energy along the tracks of the charged particles to the atoms and molecules of the tissue and ionize the atoms and molecules of that tissue. CHERNOBYL, at 37.

There are two mechanisms by which ionizing radiation can alter human cells. LAMARSH, at 409. First, the ionization can directly alter biological structures by the disruption or breakage of molecules. Id.; ICRP 60, at 96. Second, biological structures can be altered indirectly by chemical changes set in motion by the transfers of energy to the medium as the ions pass through the molecular structure of human tissue. ICRP 60, at 96. Most of this energy transfer takes place in the water of our cells simply because water is the major component of the human body.[42] MEDICAL

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42. Human cells are made up of 70% water. MEDICAL EFFECTS, at 13.

EFFECTS, at 13; BEIR V, at 12. When an ionizing particle passes through a water molecule, it may ionize it and produce an ionized water molecule, H sub2 O+, and an electron. The electron can be trapped and produce a hydrated electron, e subaq. BEIR V, at 12. However, the ionized water molecule, H sub2 O+, reacts with another water molecule to produce a free radical called the "hydroxyl radical, OH." Id.[43] This particular free-radical is very reactive because it has an unpaired electron and seeks to pair its electron in order to stabilize itself. BEIR V, at 13. At high initial concentrations, back reactions occur which produce hydrogen molecules, hydrogen peroxide and water. Id. However, the water molecule is not always ionized in this process. It can also simply become excited and break up into the hydrogen radical, H., and the hydroxyl radical, OH. Id.

The result of this chemical process is the formation of the three highly reactive species: the hydrated or aqueous electron, e subaq , the hydroxyl radical, OH, and the hydrogen radical, H. Id. All three are highly reactive and can damage the molecular structure of human cells. Id. Free radicals are produced almost immediately after an energy transfer.[44] They move rapidly in the medium, can travel some distance from the site of the original event that creates them, and they can cause chemical changes in the medium. Id. However, even though free radicals are highly reactive and potentially very dangerous to the structure of cells in human tissue most

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43. A free radical is an atom or molecule that has a single unpaired electron. MEDICAL EFFECTS, at 13.

44. A They are created in about 10-12 seconds. BEIR V, at 13.

recombine to form oxygen and water in about 10-5 seconds without causing any injury. MEDICAL EFFECTS, at 13.

Ionization radiation can damage cells whether the radiation results directly from the electrons set in motion or indirectly by the chemical production of free radicals. CHERNOBYL, at 37. A great deal of evidence suggests that DNA is the principal target in an irradiated cell, and is the most critical site for lethal damage. ICRP 60, at 96; BEIR V, at 13. DNA is believed to be the "critical cellular component injured," as low doses of radiation. MEDICAL EFFECTS, at 16. The random character of energy absorption events caused by ionizing radiation can damage vital parts of DNA in several ways including single-strand or double-strand breaks in the DNA molecule. ICRP, at 96. However, it has been postulated that the majority of DNA strand breaks are not due to the direct effects of ionizing radiation, but rather are caused by the hydroxyl radical. MEDICAL EFFECTS, at 14; see also BEIR V, at 14. Irradiation can also cause a number of recombinational changes to cells. ICRP 60, at 96.

Not all irradiation-caused damage to DNA is harmful. Cells have evolved complex repair systems and when a single-strand break occurs, it is quite possible that the site of the damage can be identified and the break very quickly repaired. Id.; CHERNOBYL, at 38. In such a case, the DNA structure is returned to its original form, and there is no long term cellular consequence. ICRP 60, at 96. For example, if ionizing radiation affects a single protein within a cell, the cell can simply produce a new protein and there is no functional change. CHERNOBYL at 37. Alternatively, the

repair may not return to DNA to its original form, but DNA integrity may be retained. Id.

While it is possible for double strand breaks in DNA to be repaired, the consequences of a double strand break are very serious. ICRP 60, at 96. Chromosomal aberrations are a result of DNA that is damaged by irradiation. These aberrations can be measured quantitatively as a function of absorbed dose. Id. at 97. The outcome could be cell reproductive death, misrepair reflected in a mutation or extensive gene deletion. Id. at 96.

If cellular damage is not repaired, it may prevent the cell from surviving or reproducing, or it may result in a viable but modified cell. CHERNOBYL, at 38. The two outcomes have severe, and different, implications for the human body, leading to either "deterministic" or "stochastic" effects. Id. Deterministic effects are entirely predictable and their severity is an inevitable consequence of a given dose. LAMARSH, at 409. Stochastic effects are those that occur at random, i.e., they are of an aleatory or statistical nature. CHERNOBYL, at 38. Thus, stochastic effects are those whose probability of occurrence, as opposed to severity, is determined by dose. LAMARSH, at 409.

i. Deterministic Effects.

Deterministic effects result when an organism can no longer compensate for the extent of dead cells by proliferating viable cells. ICRP 60, at 99. Cell death or cell killing is the main process involved in deterministic effects. Id. Unless the dose is very high, most types of cells are not

immediately killed, but continue to function until they attempt to divide. Id. The attempt to divide will fail, probably because of severe chromosome damage, and the cell will die.[45] Id. Cell death usually becomes apparent within a few hours or days after irradiation. Id. at 97.

Cell death is not always life threatening because most body organs and tissues are unaffected by the loss of even a substantial number of cells. CHERNOBYL, at 38. It is only when a tissue or organ absorbs a certain threshold dose high enough to kill or impair the reproduction of a significant fraction of vital cells within the tissue or organ that there is a clinically detectable impairment of function. ICRP 60, at 99. If enough cells are killed, the function of the tissue or organ is impaired. Id. at 97. In extreme cases the organism dies. Id. The severity of the effect is dependent on the dose. Id. Thus, the likelihood of a deterministic effect is zero at a dose lower than some threshold, but the likelihood increases to certainty above such a threshold dose, with the severity of the harm increasing with dose. CHERNOBYL, at 38-39.

Cells that divide rapidly are very sensitive to radiation and it is in these cells that the damage from radiation appears to be the greatest. KNIEF, at 75. Such cells include lymphocytes, immature bone marrow cells and intestinal epithelium. Slightly less sensitive cells include those of the lens of the eye and the linings of the stomach, esophagus, mouth and skin. Cells of intermediate sensitivity include those of the liver, kidneys, lungs, thyroid and fibrous tissue.

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45. Although individual cell death in a tissue is stochastic, the total effect of the death of a high number of cells in a tissue is deterministic. ICRP 60, at 99; CHERNOBYL, at 38.

Cells that divide slowly or not at all are the least sensitive to radiation. CHERNOBYL, at 39. These include mature red blood cells, muscle connective tissue as well as bone, cartilage and nervous tissue. Id. Thus, if a person receives a whole body absorbed dose of 1 Gy or 100 rad, generally only those cells with very high sensitivity would be killed. However, as the whole body absorbed dose is increased, additional cells and organs could die and thereby alter the person's clinical presentation. Id. Obviously, if exposure to ionizing radiation results in damage to vital organs or tissues, it may well be fatal. Id.

The likelihood of a deterministic effect is practically zero for absorbed doses below 1 Gy or 100 rad. Above that absorbed dose level, deterministic effects occur. Some examples of deterministic effects are erythema, bone marrow depression, radiation cataracts, sterility, and acute radiation syndrome. Id.; MEDICAL EFFECTS, at 280.[46]

Clinically significant bone marrow depression has a threshold for acute absorbed doses of about 0.5 Gy or 50 rad and for protracted exposure over many years of about 0.4 Gy or 40 rad per year. CHERNOBYL, at 39. Absent

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46. The threshold for temporary sterility in men for a single absorbed dose to the testis is about 0.15 Gy or 15 rad and the threshold under conditions of prolonged exposure is about 0.4 Gy or 40 rad. CHERNOBYL, at 39. The threshold for permanent sterility is 3.5 to 6 Gy or 350 to 600 rad for acute exposure and 2 Gy or 200 rad for prolonged exposure. Id. The threshold for permanent sterility in women is an acute absorbed dose between 2.5 to 6 Gy or 250 to 600 rad or a protracted dose over many years of about 0.22 Gy or 22 rad. Id.

appropriate medical care, bone marrow depression will result in half of the people in a heterogeneous population who are acutely exposed to a dose of about 3 to 5 Gy or 300 to 500 rad.[47] Id. The threshold for opacities significant enough to cause vision impairment (which occurs after some delay) appears to be in the range of 2 to 10 Gy or 200 to 1000 rad for an acute exposure to x-rays or gamma (g) rays. The threshold for chronic exposure over many years is thought to be about 0.15 Gy or 15 rad per year. Id.

Death is almost certainly the deterministic effect for an individual exposed to a whole body dose of about 6 Gy or 600 rad or higher over a short period. Id. A 3 Gy or 300 rad dose would be lethal for half of an irradiated population who receive little or no medical care, the so called "median lethal dose". Id. However, it has been postulated that for people in good health who receive very intensive medical treatment, the median lethal dose may be from 5 Gy or 500 rad to as high as 9 Gy or 900 rad. Id.

ii. Stochastic Effects.

Stochastic effects are those which result when an irradiated cell is modified rather than killed. CHERNOBYL, at 39. Even at very low doses it is possible that ionizing radiation may deposit sufficient energy into a cell to modify

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47. The estimate of the number of people who would die within a certain number of days without medical attention following a significant whole body absorbed dose is called the "lethal dose estimate" and, in this example, would be expressed as "LD50/60", meaning "Lethal Dose for 50% of the population within 60 days without medical attention." KNIEF, at 76.

it. ICRP 60, at 98. Thus, there is a finite possibility for the occurrence of a stochastic event even at very small doses. Id. Consequently, it is assumed that there is no threshold for the initiation of a stochastic event. Id., at 98; MEDICAL EFFECTS, at 73. Put another way, it is believed that stochastic effects can occur even at the lowest doses and, therefore, the possibility of a stochastic effect has to be taken into account at all doses. ICRP 60, at 67. The probability that cancer will result from radiation increases proportionally with dose. ICRP 60, at 69. CHERNOBYL, at 40. However, it is currently believed that there is no threshold dose below which the probability of cancer induction is zero. ICRP 60, at 69; CHERNOBYL, at 40. It is presumed that any transformed cell can become cancerous and become a malignant tumor. CHERNOBYL, at 40.

There are two generally recognized types of stochastic events. The first can occur in somatic cells and may result in the induction of cancer in the exposed person. The second can occur in cells of the germinal tissue and may result in hereditary disorders in the descendants of the irradiated.[48] CHERNOBYL, at 39-40; ICRP 60, at 69, 106-07. However, even though hereditary stochastic effects have been demonstrated on highly irradiated mice, CHERNOBYL, at 42, hereditary stochastic effects have not yet been clearly demonstrated in humans. BEIR V, at 4. Thus, any such effects

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48. "There are approximately 4 x 1013 cells in the average adult person .... [and they] are divided into two broad classes: somatic cells and germ cells. Almost all of the cells in the body are somatic cells. These are the cells that make up the organs, tissues, and other body structures. The germ cells, which are also called 'gametes', function only in reproduction." LAMARSH, at 406.

are based on extrapolation from mice to humans.[49] Genetic studies of the almost 15,000 children of the survivors of the atomic bombing in Japan have not yielded evidence of a statistically significant increase in severe hereditary effects. CHERNOBYL, at 42; BEIR V, at 4. Of course, the difficulties encountered in studying the probability of hereditary effects are formidable and include the need to monitor very large numbers of people in irradiated and controlled populations. The difficulty is increased because hereditary effects caused by radiation may be indistinguishable from hereditary disease due to other causes. CHERNOBYL, at 42.

It is cancer induction — the first stochastic event — that it as issue here. The cell modification caused by ionizing radiation is presumably the result of specific molecular DNA changes by a process known as "neoplastic transformation." It is assumed that there is no threshold for the induction of the molecular changes at the DNA site. ICRP 60, at 97, 107. The potential for unlimited cellular proliferation characteristically results from molecular changes. Id., at 107. Nevertheless, this change alone does not result in a malignant transformation because other changes occur in a malignant transformation. Id. Carcinogenesis is currently believed to be a multistep process requiring two or more intracellular events to transform a normal cell into a cancer cell. BEIR V, at 135. The changes that occur are believed to proceed sequentially. ICRP 60, at 97. The initial events in the production of a cell or cells with the potential to develop

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49. Such extrapolation has led to the estimate that at least 1 Gy or 100 rad of low-dose, low LET radiation is necessary to have any hereditary stochastic effect on humans. BEIR V, at 4.

into a cancer are known as "initiation". Id. The initiated cell or cells must undergo further changes, usually after a long time and possibly after stimulation by a promoting substance or catalyst, before becoming a cell with malignant potential. Id. Thereafter, the division and multiplication of such cells gives rise to an occult tumor in the "progression" stage. Id. at 97-98. "Progression" refers to the proliferation of a subpopulation of cells within a tumor. BEIR V, at 137. This subpopulation expands and overgrows the less aggressive cells. Id. The carcinogenic process, includes the growth of a primary cancer to a detectable size (e.g., about 1 cm in diameter and containing billions of cells). In humans it can take many years for such a tumor to spread to other tissues. ICRP 60, at 98.

The period between exposure to radiation and possible detection of a resulting cancer is called the "latency period". Id. at 107. By way of example, the median latency period for induced leukemia may be about 8 years. The latency period for many induced solid tumors, such as tumors of the breast or lung. Id. The "minimum latency period" is the shortest time in which a specified radiation-induced tumor is believed to occur after exposure. Id. It is about two years for acute myeloid leukemia, and between 5 and 10 years for other types of cancers. Id.

Significantly, the severity of a cancer does not depend on the level of the dose that triggered it. ICRP 60, at 60; CHERNOBYL, at 40. The mathematical model used to describe radiation induced cancer is the "linear risk model". BEIR V, at 4; CHERNOBYL, at 40. It is expressed as $y = ax$, where y is the incidence of excess cancer, a is a

constant, and x is the dose. MEDICAL EFFECTS, at 81. The linear risk model posits that each time energy is deposited in a cell or tissue, there is a probability of the induction of cancer. Id. Thus, the effect of each small dose is additive, and therefore spreading a given dose out over time does not reduce the ultimate risk. Id.

Although there is scientific consensus that ionizing radiation can cause cancer, ionizing radiation, is not currently known to leave a tell-tale marker in those cells which subsequently become malignant. NATIONAL COUNCIL ON RADIATION PROTECTION AND MEASUREMENTS, NCRP STATEMENT NO. 7, THE PROBABILITY T HAT A PARTICULAR MALIGNANCY MAY HAVE BEEN CAUSED BY A SPECIFIED IRRADIATION 1 (1992) (hereinafter "NCRP 7"). Medical examinations and laboratory tests can determine the type and extent of a cancer, suggest an optimal treatment, and provide a likely prognosis, but they rarely (if ever) provide definite information as to its cause. Id. Consequently, medical evaluation, by itself, can neither prove nor disprove that a specific malignancy was caused by a specific radiation exposure. Id. Therefore, the primary basis to link specific cancers with specific radiation exposures is data that has been collected regarding the increased frequency of malignancies following exposure to ionizing radiation. Id. In other words, causation can only be established (if at all) from epidemiological studies of populations exposed to ionizing radiation. Id.; LAMARSH, at 413.

However, the task of establishing causation is greatly complicated by the reality that a given percentage of a defined

population will contract cancer even absent any exposure to ionizing radiation. In industrialized countries where the life expectancy averages about 70 years, about 30% of the population will develop cancer and about 20% of the population will die of cancer. CHERNOBYL, at 42. It is estimated that if 100,000 persons with an age and sex distribution typical of the United States are exposed to a whole body dose of 0.1 Sv and are followed over their lifetimes, between 770-810 people would develop fatal cancers in excess of the normal incidence. BEIR V, at 6.

6. Radiation in the Environment.

The inquiry into cause is further complicated by the fact that radiation is a "constituent element" of our environment, and mankind has been exposed to it since our first appearance on this planet. CHERNOBYL, at 23. Obviously, natural environmental radiation has been, and continues to be, augmented by man-made radiation. Consequently, "the radiation environment of today differs from that of yesterday, and it will continue to be transformed in the future." Id. The total average annual dose, from both natural radiation and man-made radiation, is 3.6 mSv or 360 mrem. BEIR V, at 18.

i. Natural Radiation.

There are two major sources of natural radiation. These are cosmic radiation and terrestrial radiation. LAMARSH, at 427. Cosmic radiation is highly energetic radiation that bombards the earth from outer space. Terrestrial radiation originates in radionuclides found in the earth and in our own bodies. Id. Together, cosmic and terrestrial radiation deliver

the highest radiation dose that people normally receive.[50] CHERNOBYL, at 23.

Cosmic radiation consists primarily of a highly-energetic mixture of protons (about 87%), alpha (a) particles (about 11 percent), and a trace of heavier nuclei (about 1%) and electrons (about 1%). LAMARSH, at 427. However, the atmosphere acts as a shield, greatly weakening cosmic rays before they reach earth. MEDICAL EFFECTS, at 32. About 26 cosmogenic radionuclides have been identified. They are produced by the action of cosmic radiation. LAMARSH, at 429. However, of the 26, only tritium (3H)[51], beryllium-7 (7Be), sodium-22 (22Na) and carbon-14 (14C), contribute appreciably to irradiation, MEDICAL EFFECTS, at 32, and only carbon-14 (14C), is responsible for significant radiation doses. LAMARSH, at 429. Fortunately, carbon-14 is a relatively short-lived radionuclide.[52] It primarily results from

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50. The average annual dose of natural radiation is 2.4 millisieverts (mSv) or 240 millirems (mrems). Natural background radiation levels vary widely throughout the world. The dose of 2.4 mSv or 240 mrems is a worldwide average. However, it has been estimated that the average annual dose in the United States from natural background radiation is higher, around 3 mSv or 300 mrems, because of a reevaluation of the quantities and effects of radon gas. KNIEF, at 88. For a brief discussion of radon gas, see below.

51. Tritium is a radioactive isotope of hydrogen. There is another isotope of hydrogen call deuterium (2H) or heavy hydrogen. Deuterium is not radioactive. LAMARSH, at 8; MEDICAL EFFECTS, at 391, 396.

52. T sub1/2 = 5730 years.

the atmospheric interaction of thermalized cosmic ray neutrons and nitrogen. Id. The concentration of 14C is about the same in all living species, i.e., 7.5 picocuries per gram of carbon. Id. Because approximately 18% by weight of the human body is carbon, 14C contributes an estimated annual dose of 0.007 mSv or 0.7 mrems. Id.

The average dose of cosmic radiation at or near sea level is 0.37 mSv per year or 37 mrems per year. Id.; CHERNOBYL, at 23. However, the dose rate increases with altitude, doubling about every 1500 meters. CHERNOBYL, at 23. Consequently, people living at high altitudes[53] may have an average annual dose level reaching 1 mSV or 100 mrems. Id.

Terrestrial radiation accounts for as much as 85% of the total average annual dose of natural radiation, i.e., a little over 2.0 mSv or 200 mrems annually Id. There are approximately 340 naturally-occurring nuclides on earth, and of these, about 70 are radioactive. LAMARSH, at 429. They are called primordial radionuclides because they have existed in the earth's crust since the earth was formed. Id. Those now present on earth have half-lives comparable to the age of the universe. MEDICAL EFFECTS, at 33. Accordingly, primordial radionuclides with half-lives of less than about 108 years can no longer be detected. Id. Primordial radionuclides with half-lives of more than 1010 years have decayed very little up to now. Id.

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53. For example, Denver, Colorado or Bogota, Colombia. CHERNOBYL, at 23.

Appendix A

Primordial radionuclides produce secondary radionuclides through the process of radioactive decay. There are three distinct chains of primordial radionuclides: (1) the uranium series, which originates with 238U; (2) the thorium series which originates with 232Th; and (3) the actinium series, which originates with 235U. Together, the parent of each chain and its respective daughter products contribute significantly to terrestrial irradiation. Id.

Uranium is found in various quantities in most rocks and soils, and it is the main source of radiation exposure to people out-of-doors. CHERNOBYL, at 23. The uranium isotopes are alpha (<<alpha>>) particle emitters and, therefore, they do not contribute to gamma (<<gamma>>) ray exposure.[54] MEDICAL EFFECTS, at 33. Since uranium isotopes are generally present in low concentrations, they do not contribute significantly to the internal alpha (<<alpha>>) ray dose delivered to humans. Id. However, since these isotopes are found in soil and fertilizers, they migrate into our food chain, and therefore, into our tissue. Id. at 35.

Another significant source of terrestrial radiation exposure is radium-226 (226Ra) — an isotope which originates in the uranium series — and its daughter products. Radium-226, with a half-life of 1622 years, is an alpha

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54. Naturally occurring uranium consists of three isotopes, 234U, 235U and 238U. Uranium-238, the parent of the uranium series is the most abundant isotope, present in the amount of 99.28%, and it is in equilibrium with 234U, which is present in the amount of 0.0058%. Uranium-235, present in the amount of 0.71%, is the parent of the actinium series. MEDICAL EFFECTS, at 33.

(<<alpha>>) emitter and is present in all rocks, soils and water. Id. Radium is chemically similar to calcium and it passes through the food chain into humans because plants absorb it from the soil.[55] The annual dose attributable to the intake of 226Ra is 7 microsieverts (Sv) or 0.7 mrem. Id. at 36.

Approximately 95% of the world's people live in areas where the annual average dose from outdoor external radiation sources is about 0.4 mSv or 40 mrems. CHERNOBYL, at 24. However, there are areas in the world where people are exposed to very high levels of terrestrial radiation. For example, thorium- rich monazite sands in certain areas of Brazil and India also have exceptionally high levels of irradiation. LAMARSH, at 429.[56]

Radium-226 is also an important source of terrestrial radiation exposure because it decays to radon-222 (222Rn), a noble gas radionuclide with a half- life of 3.8 days that emits alpha (<<alpha>>) particles and contributes to gamma (<<gamma>>) radiation through its gamma-emitting descendants. Id. Radon is an odorless, colorless, nonreactive gas that poses no significant biological threat. Id. Alpha (<<alpha>>) particles emitted by radon outside the body do not penetrate skin. Id. However, the daughter elements formed as radon decays can be a significant source of natural

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55. In the human body, 70% to 90% of radium is found in bone. MEDICAL EFFECTS, at 35.

56. Similarly, in Guarapari, Meaipe and Pocos de Caldas in Brazil, exposure dose rates can be 100 times the norm, and in the coastal areas of Kerala and Tamil Nadu in India, exposure rates can be 1000 times higher than the norm. CHERNOBYL, at 24.

irradiation and potential biological damage. CHERNOBYL, at 24. Once inhaled, the radon daughters may be deposited in the tracheo-bronchial tree. Id. Some of the radon daughters — the polonium isotopes, 218 (radon A) and 214 (radon C1) — emit alpha (<<alpha>>) particles. 218Po (radon A) provides the major alpha (<<alpha>>) particle dose to the tracheo-bronchial tree, and it therefore poses an increased risk of lung cancer. CHERNOBYL, at 24.

Because it is a noble gas, radon diffuses from its point of origin. LAMARSH, at 430. Moreover, because it is the immediate daughter product of the decay of radium-226 (226Ra), it can be present in radium-bearing rocks, soils and home construction materials. Id. at 429-30. Radon enters buildings primarily through the underlying and surrounding soils and, secondarily from building materials, outdoor air, tap water and natural gas. CHERNOBYL, at 24. Since concentration increases in enclosed spaces, radon concentration is much higher indoors than outdoors. MEDICAL EFFECTS, at 37-38. Radon is the largest contributor to terrestrial radiation because people spend most of their time indoors.[57] Levels of radon in the air vary from place to place, season to season, day to day and hour to hour. Id.

Both lead-210 (210Pb) and polonium-210 (210Po), which, as noted above, are decay products of radon-222 (222Rn), are introduced into the human body through inhalation as well as through the food chain. LAMARSH, at

57. It is responsible for more than half of the natural radiation we are exposed to, i.e., 1.3 mSv per year or 130 mrems per year. CHERNOBYL, at 24.

429-30. 222Rn is a noble gas and therefore, tends to diffuse into the atmosphere where it can travel large distances before decaying into 210Pb. Id. at 430. 210Pb is not inert and attaches to dust and moisture particles in the atmosphere soon after it is formed. Consequently, it can be inhaled directly into the body or fall onto leafy vegetables or pasture grasses from where it can enter the food chain. Id. at 430, 433. Lead-210 does not lead to significant internal radiation doses because it is a rather weak beta (<<beta>>) particle emitter. However, its daughter product, 210Po, is a powerful, highly-energetic alpha (<<alpha>>) particle emitter and it provides very significant doses of radiation. Id. at 431.

Because both radionuclides can enter the body through ingestion, internal radiation exposure is influenced by dietary patterns. CHERNOBYL, at 24. For example, both radionuclides are present in seafood thus, in countries such as Japan, where seafood is a dietary staple, annual intakes of both radionuclides are significantly higher than in countries where seafood is not a staple. Id. Both radionuclides concentrate in lichens. Accordingly, people in the extreme northern hemisphere who eat the meat of animals that graze on lichens (caribou and reindeer) have levels about ten times higher than the norm. Id. Both 210Pb and 210Po are found on broad leaf tobacco plants, Id. at 433. Both of these radionuclides have also been detected in commercial tobacco products and in cigarette smoke. CHERNOBYL, at 24.

There is a dispute within the scientific community as to whether background radiation produces stochastic effects. The International Commission on Radiological Protection assumes that stochastic effects may be induced by natural

radiation and man-made radiation. ICRP 60, at 93. It has been inferred that about 3% of cancer deaths each year in the United States are attributable to background radiation, with 1.5 to 2% due to natural radiation, 0.5% to medical uses and 1% or less to occupational sources. See Luis Felipe Fajardo, Ionizing Radiation and Neoplasia, in NEW CONCEPTS IN NEOPLASIA AS APPLIED TO DIAGNOSTIC PATHOLOGY 99 (Cecilia M. Fenoglio-Preiser, Ronald S. Weinstein and Nathan Kaufman, eds., 1986). However, it has also been reported that natural background has not yet been proven to be cancer inducing, and, some scientists claim that natural background radiation does not cause cancer. Id.

ii. Man made Radiation.

Here, of course, we are most directly concerned with radiation from the nuclear power plant at TMI. It is undisputed that the production of electricity by nuclear power can add to the radioactivity in our environment. Irradiation occurs in the production of electricity, and in all stages of the fuel cycle, i.e., mining, fuel fabrication, transportation, reactor operation and reprocessing CHERNOBYL, at 26-27. However, under normal circumstances, and without considering the effect of nuclear power plant accidents, the overall impact of nuclear power generation on the total population is reported to be very small. MEDICAL EFFECTS, at 45.

There are three major sources of man-made radiation other than nuclear power plants. These are: industrial processes other than nuclear power generation that also use

radionuclides, medical irradiation, and nuclear weapons testing. CHERNOBYL, at 24.

Medical irradiation is generally divided into three categories: (1) diagnostic x-ray examinations; (2) the use of radio pharmaceuticals in nuclear medicine; (3) therapeutic applications of radiation. MEDICAL EFFECTS, at 47.[58]

Nuclear weapons testing occurs either above ground ("atmospheric testing"), or underground.[59] Radionuclides released in atmospheric testing can enter the body directly or be deposited on the earth's surface from whence they may later be absorbed via the food chain, or be absorbed through by way of external radiation. MEDICAL EFFECTS, at 44.

Generally, estimates of human exposure to fallout are more concerned with atmospheric (and more particularly stratospheric), fallout than with local or tropospheric fallout because radionuclides in the stratosphere result in fallout worldwide. Id. In fact, stratospheric particulate fallout

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58. The average annual dose due to medical irradiation is between 0.4 and 1 mSv or 40 to 100 mrems. CHERNOBYL, at 47. Of the three categories of medical irradiation, diagnostic x-ray examinations account for almost 95% of the total dose received. Id.

59. Atmospheric testing began in 1945. From then until 1980 there were more than 400 nuclear weapons tested in the atmosphere. CHERNOBYL, at 25. In 1963, the United States, the United Kingdom, and the former USSR entered into the Partial Test Ban Treaty, and undertook to cease atmospheric testing. However, France and China continued atmospheric testing. Id. All of the atmospheric tests released significant amounts of radioactive material into the environment. CHERNOBYL, at 47.

accounts for most of mankind's worldwide exposure to fission products. Id. Fallout consists of numerous radioactive by products of atomic reactions. However, only four of these have half-lives of sufficient length to be of significant concern to present and future populations: 14C, with a half-life of 5730 years; 137Cs and 90Sr, both with a half-life of 30 years; and 3H, with a half-life of 12 years. CHERNOBYL, at 25. 14C provides almost two-thirds of the dose exposure because of the relatively short half-lives of the other three radionuclides. Id. The average annual dose to individuals from atmospheric testing is 0.01 mSv or 1 mrems. Id. There have been approximately 1300 underground nuclear weapons tests. MEDICAL EFFECTS, at 44. However, a well-contained underground explosion delivers little, if any, radionuclides to the environment, except for occasional venting. Id.

Industrial processes, such as electricity production, mining, and the use of certain building materials and fertilizers produce above average concentrations of natural radionuclides. CHERNOBYL, at 25. Coal contains more radionuclides than other fossil fuels and burning coal produces a large amount of particulate emissions. MEDICAL EFFECTS, at 39. Other sources of industrial irradiation include certain consumer products, such as luminous timepieces, electronic and electrical devices, video display terminals, antistatic devices, and smoke detectors. MEDICAL EFFECTS, at 42. However, tobacco products probably contribute the greatest radiation dose of all consumer products. Id. at 43. It has been postulated that the radionuclides 210Pb and 210Po are responsible for the high incidence of lung cancer in smokers. BEIR V, at 19; LAMARSH, at 433.

Appendix A

It is generally conceded that atmospheric weapons testing has contributed more to man-made radiation than nuclear power plants. Id. at 45. On average, the annual dose from all facets of the nuclear fuel cycle is less than 0.1% of that from natural radiation, CHERNOBYL, at 26, or less than 10 mSv or 1 mrem a year. KNIEF, at 88. In fact, it has been postulated that atmospheric releases of radionuclides from fossil fuel plants, especially coal plants without scrubber systems, may be greater than the releases of radionuclides from nuclear power plants. MEDICAL EFFECTS, at 45.

Nevertheless, it is beyond dispute that nuclear power plants in general, and nuclear accidents in particular, can release harmful radioactivity into the environment. Irradiation occurs not only in the production of electricity but in all stages of the fuel cycle, i.e., mining, fuel fabrication, transportation, reactor operation and reprocessing CHERNOBYL, at 26-27.[60]

Accordingly, before proceeding with our discussion of the District Court's application of Daubert to the expert testimony that was offered to prove that TMI-2 released radiation that caused the Trial Plaintiffs' neoplasms we will briefly discuss the operation of a nuclear power plant in an effort to better determine if Trial Plaintiffs proffered sufficient evidence to connect their injuries to the nuclear reactions that took place inside the nuclear generator at TMI-2. For purposes of assessing the Daubert challenges to

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60. Under normal circumstances, and without considering the effect of nuclear power plant accidents, the overall impact of nuclear power generation on the total population is reported to be very small. MEDICAL EFFECTS, at 45.

the experts in this case, we will limit our discussion of nuclear fission to reactions initiated by neutrons.[61]

IV. NUCLEAR ENGINEERING

A. Nuclear Reaction.[62]

The bulk of electricity generated in the United States is the result of thermal energy (i.e., heat) produced in either fossil-fueled boilers or nuclear power plants. ANTHONY V. NERO, JR., A GUIDEBOOK TO NUCLEAR REACTORS 3 (1979). Nuclear power plants generate energy through nuclear fission. Id. Nuclear fission provides nearly one hundred million times as much energy as the burning of one carbon atom of fossil fuel. KNIEF, at 4. Fission therefore has obvious advantages over fossil-fuel based energy production. It has been estimated that the complete fission of just one pound of uranium would release approximately the same amount of energy as the combustion of 6,000 barrels of oil or 1,000 tons of high-quality coal. NERO, at 4. However, the major disadvantage of the fission process is now painfully obvious. It requires mankind to harness and control one of the most awesome physical powers in the universe. In addition, potentially deadly radioactive materials are produced in the process. KNIEF, at 4.

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61. Charged particles and gamma (<<gamma>>) rays can also induce fission, but they are not significant for our purposes because neutron induced fission is the basis of commercial nuclear power, KNIEF, at 41, and it is that fission that occurred at TMI.

62. The general term "nuclear reaction" describes any of a wide number of interactions involving nuclei. BODANSKY, at 46.

Appendix A

Neutron interactions with nuclei are possible because the absence of a charge allows a neutron to approach a nucleus without repulsion from an opposing force. BENNET, at 23. The important reactions occur at relatively low energies and include "elastic scattering", "inelastic scattering", "neutron capture" and fission. BODANSKY at 46. Chance determines which of these reactions occur for a given neutron. Id. at 48.

In elastic scattering, a neutron and nucleus collide without any change in the structure of the target nucleus. Id. It is, therefore, like "the collision of two billiard balls of unequal mass." BENNET, at 23. Although the structure of the nucleus is unchanged in elastic scattering, the laws of motion cause the neutron to change direction and speed and the nucleus recoils. BODANSKY, at 47. The total kinetic energy of the system is unchanged, but some of the neutron's energy is transferred to the target nucleus. Id. Elastic scattering can occur with any target nucleus, but in nuclear reactors it is most significant when the target nucleus is relatively light, and the loss of kinetic energy is, therefore, relatively large. Id. In that scenario, elastic scattering effectively reduces the energy of the neutrons without depleting their number.

Inelastic scattering differs from elastic scattering because the target nucleus is left in an excited state. Id. The target nucleus decays, usually quickly, to the ground state with the emission of gamma (<<gamma>>) rays. The total kinetic energy of the neutron and the target nucleus after the scattering is less than that of the neutron before the scattering, with the difference equaling the energy of the gamma

(<<gamma>>) rays. Id. An important characteristic of inelastic scattering is that neutrons lose on average much more energy per collision than they do in elastic scattering. BENNET, at 28.

In neutron capture, which occurs in the first stage of many reactions, the neutron combines with the target nucleus to form an excited compound nucleus. BODANSKY, at 47. The term "neutron capture" is usually restricted to cases where the excited compound nucleus decays by the emission of gamma rays.[63] Id. The number of gamma rays emitted in the de-excitation varies. Id.

Neutron capture can occur for almost any target nucleus and it plays two general roles in nuclear reactors. First, it consumes neutrons that might otherwise initiate fission. Second, it transforms nuclei produced in fission into other nuclei. Id. Further, as will be discussed below, the reaction is significant because it is the first step in the production of plutonium-239 in reactors. Id.

As noted earlier, a nuclear reactor produces energy from fission. However, fission is possible for only a very few target nuclei, the most important being isotopes of uranium and plutonium. Id. at 48. If an appreciable fission yield is produced by neutron incidents upon a target nucleus, that

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63. An example is:

formation: n + 238U — > 239 U*
de-excitation: 239U* — > 239U + <<gamma>>'s

BODANSKY, at 47.

nuclear species is termed fissile. Id. at 61. In a typical fission reaction, the excited compound nucleus divides into two fragments plus several neutrons.[64] Id. at 48. The energy released in fission comes from the large kinetic energy of the fission fragments. Id. An average fission event produces nearly 200 million electron volts of energy (200 MeV). KNIEF, at 45. In contrast, approximately 2-3 electron volts (eV) of energy is released for each carbon atom burned with oxygen. Id. Neutrons produced by the fission event have an average energy of 2 million electron volts (2 MeV). BENNET, at 55. The fission fragments come to rest within about 10-3 centimeters of the fission site so that all of their energy is converted into heat. LAMARSH, at 76. It is important to remember that the fission products are all radioactive. BENNET, at 30. The formation of each fission product is followed by a series of beta decays that continues with successive emission of <<beta>>- particles until a stable isobar is reached. BODANSKY, at 48. In addition, gamma rays are emitted in the de-excitation of the fission fragments, assuming they are formed in excited states, as well as in the de-excitation of the products of the successive <<beta>>- decays. Id.

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64. A typical fission reaction illustrated for a 235U target is of the general form:

$$n + {}^{235}U \longrightarrow {}^{236}U^* \longrightarrow {}^{144}Ba + {}^{89}Kr + 3n.$$

The products in this example are barium 144 (atomic number Z = 56), krypton 89 (Z=36), and 3 neutrons. BODANSKY, at 48. Many other outcomes are also possible, always subject to the condition that the sums of the atomic numbers of the products are the same as those of the initial system. Id. Both the 144Ba and 89Kr nuclei are radioactive. Id.

Appendix A

The release of significant amounts of energy from fission requires a chain reaction. Id. at 69. Fission forms the backbone of the required chain reaction. NERO, at 5. Earlier, it was noted that neutrons produced by fission in the uranium fuel have an average energy of 2 MeV. However, fission in uranium will not result in a chain reaction if the neutrons interact at energies close to those in which they were emitted. BODANSKY, at 73. Consequently, it is necessary to reduce the energy of the neutrons from this average energy region to a more favorable region below 1 electron volt (eV) by elastic collisions with the nuclei of a moderator. Id. Commonly used moderators are hydrogen in water, deuterium in heavy water or carbon in graphite. Id. at 74. After a sufficient number of elastic collisions with the moderator, the neutrons have reached a low or "thermal energy" and a chain reaction can occur. NERO, at 7.

A chain reaction is sustained by the emission of low energy neutrons from fissioning nuclei. BODANSKY, at 50. A nuclear reactor such as TMI-2 is "merely" the system in which a controlled chain reaction takes place. LAMARSH, at 103. In order for a self-sustaining chain reaction to occur, at least one of the neutrons produced in one fission event must cause a second fission event from which one neutron causes a third fission event, and so on. Id. at 102. Each such generation must have more fission events than the preceding one if a continuing and useful chain reaction is to occur. BODANSKY, at 69.[65] The condition for establishing a chain

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65. The average number of neutrons emitted in fission is crucial for establishing the practicality of a chain reaction. Id. at 64. The number of neutrons varies from event to event, ranging from 0 to

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reaction is commonly expressed as the "achievement of criticality". Id. "Criticality" is described quantitatively in terms of the multiplication factor, denoted by the symbol k, LAMARSH, at 102, or the criticality factor, BODANSKY, at 69, which is defined as the ratio of the number of fissions (or fission neutrons) in one generation divided by the number of fissions (or fission neutrons) in the preceding generation. LAMARSH, at 102. A system is critical if k equals 1. Id. If k is greater than 1, the system is "super critical," "and a divergent chain reaction exists in which the neutron density and fission rate increase, possibly at an explosive rate as in an atomic bomb." BENNET, at 54. If k is less than 1, the system is "subcritical" and the chain reaction decreases and eventually stops. Id.

In a nuclear reactor, the operator can vary the value of k by varying the rate at which neutrons are produced within the reactor with the rate at which they are absorbed or disappear.[66] LAMARSH, at 103. To increase the power being produced by the reactor, the operator increases k to a value greater than 1 so that the reactor becomes supercritical. Id. When the desired level has been reached, the operator adjusts k to one so that the reactor is critical and maintains the desired level. Id. To reduce power or shut the reactor down, the

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about 6. Id. Generally 2 or 3 neutrons are emitted per event. Id. The excess is necessary because some neutrons will be lost to capture reactions and other neutrons will leave the region where the chain reaction is to be established. Id.

66. Nuclear bombs and explosives cannot be controlled in this way and therefore are not called reactors. LAMARSH, at 103.

operator reduces k to less than 1, making the reactor subcritical. Id.

Earlier, we noted that neutron capture wastes neutrons if we consider only fission. However, neutron capture plays an important role in reactors because through it nonfissionable nuclei become fissile. BODANSKY, at 61, 78. Neutron capture in thorium-232 (232Th) and uranium-238 (238U) leads, with intervening <<beta>>-decays, to the production of the fissile nuclei uranium-233 (233U) and plutonium-239 (239Pu). Id. at 61. Therefore, 232Th and 238U are termed fertile. Id. Where uranium is used as the fuel, plutonium-239 (239Pu) is ultimately produced by the capture of neutrons in fertile uranium-238 (238U). The 239Pu can be used for the production of atomic weapons or in other reactors. BODANSKY, at 78. It also contributes fissile material which is consumed in the reactor before the fuel is removed, supplementing the original fissile 235U in the fresh fuel. Id. Essentially, through neutron capture, the fertile nuclei become fissile nuclei enabling the nuclear reaction to continue in the reactor.

B. The Operation of Nuclear Power Plant.[67]

At its most elementary level, a nuclear reactor is a deceptively simple apparatus. Simply put, a nuclear power

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67. The following description is taken, for the most part, from two sources — the affidavit of a defense expert witness and a report commissioned by the Nuclear Regulatory Commission. We rely on these sources because appellants have not provided us with any evidence of the workings of a nuclear power plant, and because the (Cont'd)

plant produces heat energy that is converted to steam in a boiler. Affidavit of John A. Daniel at ¶17. The steam is used to turn a turbine, which is connected to, and turns an electrical generator that produces electrical power. Id. The apparent simplicity of this basic operation is made even more deceptive when one considers the awesome power of the forces at work within nuclear reactors such as TMI-2. However, beyond this elementary level, a nuclear power plant is an extraordinarily complex system. The heat energy is produced in a vessel called a "reactor," because it contains the nuclear reactions. Id. The reactor vessel is a steel pressure vessel with walls that are 8-1/2 inches thick, surrounded by a concrete and steel shield over 8 feet thick. Id. at 23.

The TMI-2 nuclear reactor at issue here was a standard Babcock & Wilcox pressurized water reactor ("PWR").[68] It

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basic operation of a nuclear power plant is not in dispute. See 927 F.Supp. at 846. The affidavit is of John A. Daniel, a nuclear engineer who is currently a consultant to the nuclear power industry, and can be found in the Consolidated Appendix at 14759-14889. The government report is MITCHELL ROGOVIN, NUCLEAR REGULATORY COMMISSION INQUIRY GROUP, NUREG/CR-1250, TMI REPORT TO THE COMMISSIONERS AND TO THE PUBLIC AT 10-13 (1980).

68. The physical plant of a PWR nuclear power plant consists of a reactor building, a turbine building, an auxiliary building, a fuel handling building and a control and service building. Daniel Aff. at ¶23. The reactor vessel, pressurizer, associated piping, reactor coolant pumps and steam generators are collectively referred to as the "reactor coolant system" and are located in the reactor building.
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used uranium dioxide (U02) as a fuel. Id. at PP 17, 18; J.A. Daniel, Noble Gas Transport During the TMI-2 Accident (1993) 87. The UO sub2 is formed into ceramic pellets, each of which is about one-half inch in diameter. Daniel Aff. at ¶17. Fuel pellets are stacked into metal rods called "fuel pins", which are arranged into square "fuel assemblies." Id. The fuel assemblies are approximately twelve feet high, contained in the reactor, and are collectively referred to as the "reactor core". Id. The fuel assemblies contain several control rods with instruments, some of which monitor the reactor, and others which speed up or slow down the reaction. Id. These control rods contain materials with large thermal neutron absorption capacities. BODANSKY, at 80. The rods

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Id. The reactor building is actually a large pressure vessel designed to withstand the pressure increase which would result if there was a rupture in reactor coolant piping. Id. at ¶24. During the plant's operation, the reactor building is kept air tight and access to the building is through personnel air locks, similar to those used on spacecraft. Id.

The turbine, condenser and electrical generator are housed in a concrete and steel building called the "turbine building". Id. at ¶23. The auxiliary building contains the auxiliary systems used to process and maintain the chemical and radiological purity of the reactor coolant. Id. The fuel handling building houses the storage facilities for new and used fuel. Id. After it is removed from the reactor core, the used fuel is stored underwater in the "spent fuel pool." Id. The auxiliary and fuel handling buildings have redundant air filtration units which are designed to remove filterable radioactive particles before being discharged to the environment. Id. The plant operations personnel monitor and maintain control of the various plant systems from a central control room located in the control and service building. Id.

are either inserted or withdrawn to maintain the appropriate level of criticality, (where k equals 1), and enable the reactor to operate at steady power for long periods of time. BENNET, at 107-08. The reactor contains water some of which serves to cool the reactor during the nuclear reaction, and some of which is heated to steam by the chain reaction. The fuel rods containing the uranium fuel are sheathed in rods that prevent the fuel pellets from coming into direct contact with the water in the reactor core and are called the fuel cladding. MITCHELL ROGOVIN, NUCLEAR REGULATORY COMMISSION INQUIRY GROUP, NUREG/CR-1250, TMI REPORT TO THE COMMISSIONERS AND TO THE PUBLIC 10 (1980) (hereinafter "NUREG/CR-1250"). Daniel Aff. at ¶17.

The nuclear reaction in the core is generated by a neutron source which emits neutrons in a manner designed to initiate a chain reaction. Most fission products are solid at fuel temperature, but some are gases. Id. at ¶18. Some of the fission products, especially the noble gases krypton and xenon, migrate to the edge of the fuel pellet and collect in the space between the fuel and the cladding. Since some of the fission products may escape from the cladding into the water in the reactor, the reactors are designed to contain cooling water within its own closed loop. Id.

In a PWR of the TMI-2 type, there are three cooling systems. Daniel Aff. at ¶ 19. A PWR coolant system[69] is a circuit or closed loop of distilled water with a small amount of boric acid. NUREG/CR-1250 at 10. The primary circuit,

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69. There are two virtually identical coolant loops in the TMI-2 reactor, called the "A" and "B" loops. NUREG/CR-1250 at 11.

called the "primary coolant" or "reactor coolant", circulates water through the reactor core. Daniel Aff. at ¶19. During normal reactor operation, the water in the primary coolant is kept at an average temperature of 575 <<degrees>> F and pressures high enough, (around 2200 pounds per square inch), to keep the water from boiling to steam. NUREG/CR-1250 at 10. The water in the primary coolant circulates and recirculates through this loop. Id. While it is circulating and recirculating, the primary coolant water picks up heat from the fission reaction in the reactor core and carries the heat from the core through two "hot leg" pipes to two steam generators. Daniel Aff. at ¶19; NUREG/CR-1250 at 10. The steam generators are tanks, approximately 35 feet tall, in which the primary coolant water passes through a large number of narrow tubes that transfer heat to water contained in another, separate circuit, called the "secondary circuit" or "feedwater loop." Daniel Aff. at ¶19; NUREG/CR-1250 at 10. The water in the secondary circuit, called "feedwater," is maintained at a lower pressure than the water in the primary coolant circuit, Daniel Aff. at ¶ 19, allowing the feedwater to boil to steam. Id.; NUREG/CR-1250 at 10. The steam in the secondary circuit is called the "main steam system". Daniel Aff. at ¶19.

The primary coolant water, having lost some of its heat in the secondary circuit, is then returned to the reactor core through four pipes, known as "cold legs." NUREG/CR-1250 at 11. Once the primary coolant water is returned to the reactor core, it is heated once again by the nuclear reaction, and the cycle repeats. Id. The primary coolant water is kept moving at high speed in the primary circuit by four reactor coolant pumps — enormous devices each of which requires

enough electricity for its own operation to light a small town. Id.

At a point between the reactor and the steam generator, there is a pipe leading to the bottom of a large vessel or tank called a "pressurizer". NUREG/CR-1250 at 11. During normal operation, coolant water does not circulate back and forth through this pipe. Id. The pressurizer is normally kept a bit more than half full of coolant water. Above the water is a cushion, or "bubble," of steam. Id.; Daniel Aff. at ¶20. The pressurizer is a means of keeping the pressure in the reactor coolant system relatively constant, to prevent the reactor coolant water from boiling. NUREG/CR-1250 at 11. The steam cushion at the top of the pressurizer can be made larger or smaller by slight heating or cooling of the pressurizer water just beneath it. Id. When the bubble temperature and pressure are increased, the bubble tends to push water from the pressurizer out into the primary reactor coolant loop, thereby increasing pressure in the loop. Id. When the temperature and pressure in the pressurizer are lowered, steam condenses and the bubble shrinks. Id. Consequently, water tends to come from the reactor coolant loop into the pressurizer, and the overall system pressure is lowered. Id.

A relief valve, referred to as a "power-operated relief valve" ("PORV"), is located in a pipe leading out of the top of the pressurizer, at the top of the space normally occupied by the steam bubble. Daniel Aff. at ¶ 21, NUREG/CR-1250 at 11. The PORV is designed to open automatically when the system begins to over pressurize. NUREG/CR-1250 at 11. Theoretically, if the pressure in the coolant system rises

very abruptly, the PORV will open, some of the steam will rush out to a drain tank, thus shrinking the bubble, more water will move up into the pressurizer from the primary coolant loop, and system pressure will decrease. Id.; Daniel Aff. at ¶21. A rupture disk is provided on the drain tank to relieve pressure if the drain tank becomes too full. Daniel Aff. at ¶21. When the system pressure is back to normal, the PORV is supposed to close automatically. NUREG/CR-1250 at 11. If the PORV fails to close, there is a backup, called a "block valve". Daniel Aff. at ¶ 21. There are two other safety valves in addition to the PORV. NUREG/CR-1250 at 11; Daniel Aff. at ¶21.

The heart of the secondary circuit or feedwater loop is the steam generator. NUREG/CR-1250 at 11. After the water in the secondary circuit is heated to steam by the hot water from the primary coolant system, the steam moves through the secondary circuit or feedwater loop to a steam turbine which turns the power generator that produces the electricity. NUREG/CR-1250 at 11. The steam then passes through a condenser, where it is cooled and condensed into water once again and recycled through the steam generators. Id. at 11-12. The pipe line returning the water from the condenser to the steam generator also contains the condensate polishers or "demineralizers". Id. at 12. The demineralizers are basically water softeners, that use ion exchange resins to purify the feedwater. Id.

The condenser itself is cooled by water from the third circuit, i.e., the cooling towers, Id. at 12; Daniel Aff. at ¶19, which are the familiar landmarks of nuclear plants. The water in the condenser circuit, having been warmed in the process

of condensing steam back into water, is pumped up to the cooling towers. NUREG/CR-1250 at 12. The condenser water is thus cooled by exposure to the atmosphere as it tumbles down a steep run of steps and then is pumped back into the condensers. Id. The escaping water vapor is the plume or cloud which can often be seen coming out of the cooling tower. Id.[70]

In addition to the systems peculiar to a PWR, the TMI-2 reactor had a general safety system common to all reactors called the "emergency core cooling system" ("ECCS"), which is designed to supply cooling water to the hot reactor core if there is a loss of water due to a break in the reactor coolant system. NUREG/CR-1250 at 12. If the break is small, the leakage flowing from the break may not be significant and the system's internal pressure will stay high, making it difficult for the ECCS to pump water in. Id. Consequently, the plant has high pressure injection ("HPI") pumps to deliver water from a large borated water storage tank ("BWST"). Id. However, the HPI pumps are not able to deliver enough water if the break is large. Id. Therefore, the system has a

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70. During this process, chemicals may be added to the reactor coolant to fine tune the nuclear reaction in the reactor core, and to remove any impurities that may have collected in the coolant. Daniel Aff. at ¶22. During power operations, a small flow of reactor coolant is bled off from the reactor coolant system and passed through a series of filters and demineralizers. Id. If additional water is needed in the reactor coolant system, it is added from water stored in tanks located in an auxiliary building. Id. The system that collects water from the reactor coolant system and adds water to the reactor coolant system is called the "makeup and purification system". Id. Any gases collected from the reactor coolant system are collected in waste gas decay tanks. Id.

set of low pressure injection ("LPI") pumps that can deliver water to the core rapidly when a large pipe break has caused the system's internal pressure to drop. Id. The LPI pumps also draw water from the BWST. Id.

The LPI pumps also have another purpose. When a reactor is shut down, the radioactive waste in the fuel continues to produce a considerable, but diminishing, amount of decay heat for days following shutdown. This heat must be removed if the core is to be kept from melting. Id. Even after the reactor is shut down, the accumulated fission products continue to decay and release energy within the reactor. LAMARSH, at 350. This fission product decay is called "decay heat". Id. A method for handling the decay heat and for cooling the reactor core after shutdown must be provided or the temperature of the fuel may rise to a point where the fuel's integrity is compromised and fission products are released. Id.

After shutdown, the reactor is first cooled by the continued normal operation of the steam generators until the reactor coolant system is cooled to a temperature of about 300 <<degrees>> F and an internal system pressure below 400 psi. NUREG/CR-1250, at 12. Then, valves are opened to let one of the LPI pumps circulate coolant through the reactor core and out to a special heat exchanger to bring the system temperature down to about 120 <<degrees>>-140 << degrees>> F. Id.[71]

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71. The LPI system is called the "decay heat removal system" when it performs this function. NUREG/CR-1250 at 12.

Finally, there is an ECCS system called the "core flood tanks." These are two tanks almost completely filled with water under a medium-pressure of about 600 psi. Id. They stand above the reactor and a check valve prevents the higher reactor core system pressure from driving more water into them. Id. If a large pipe break occurs, it takes a few minutes for the HPI and LPI pumps to deliver cooling water to the core. Id. Therefore, the coreflood tanks are designed to drop their thousands of gallons of water to cool the core until the HPI and LPI pumps deliver cooling water. Id.

C. Barriers to Release of Radioactive Materials into the Environment.

A nuclear reactor must obviously have barriers designed to prevent the fission products from entering the working areas of the reactor or escaping into the environment. NUREG/CR-1250 at 342. The first such barrier is the ceramic fuel matrix in which the fission products are produced. Id. The uranium dioxide (UO2) used in the TMI-2 reactor is a ceramic fuel which has microscopic boundaries ("grain boundaries") between the molecules. Daniel, Noble Gas Transport at 87. These boundaries serve as microscopic roadways for certain fission products to travel out of the fuel. Id. Thus, some of the elements that are volatile or gaseous at the operating temperature of the fuel are able to migrate through the ceramic fuel. NUREG/CR-1250 at 342. However, the majority of the fission products that are produced are either trapped or chemically bound. Id.

The second barrier to the release of fission products is the fuel cladding. The UO2 ceramic pellets are sealed in the

fuel rods to prevent the fuel pellets from directly contacting the water in the reactor core. There is a small gap between the fuel and the fuel cladding. Noble gases such as krypton and xenon, and other volatile nuclides are contained in that gas. However, if a defect or rupture develops in the fuel cladding, volatile fission products can be released into the coolant. Id. at 343. At the time of the TMI-2 accident, the Nuclear Regulatory Commission generally allowed operation of a reactor with up to 1% of the fuel having a defect in its cladding.[72] Id.

The third barrier is the reactor coolant. Many of the volatile fission products, the radio iodines and radio halogens, are soluble in the coolant in "ionic" (electrically charged) form. Id. at 343. These materials can be removed by demineralizers, such as those in the makeup and purification system of the reactor, or they may remain dissolved in the coolant. Id. The majority of these radionuclides are contained in the primary coolant system, Id., and are soluble in the coolant. Id. Their solubility decreases and they tend to precipitate or "plate out" as the pH of the primary coolant is increased. Id. The noble gas radionuclides, kryptons and xenons, have very low solubility in the coolant, particularly in the presence of other gases such as hydrogen, and they evolve into a gas or vapor phase above the coolant or wherever the coolant is depressurized. Id.

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72. Even in the absence of defective fuel elements, a small background concentration of fission products exists in the primary coolant system, because of the fissioning of trace quantities of uranium ("tramp uranium") in or on the fuel cladding material. NUREG/CR-1250 at 342.

The fourth barrier is the reactor pressure vessel and the piping of the primary coolant system, which are made of heavy walled steel. Id. The fifth barrier is the containment building itself. It is designed to withstand over pressurization and external impacts and contain or delay fission product releases during an accident. Id.

V. THE ACCIDENT AND ITS AFTERMATH

A. The Accident at TMI-2.[73]

What has been described as the "[n]ation's worst nuclear accident"[74] began at about 4:00 a.m. on Wednesday, March

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73. Although the defendants have previously conceded that radioactivity was released into the environment as a result of the TMI-2 accident, see 67 F.3d at 1119, there is apparently some dispute about the "specific operation of the TMI-2 PWR during the accident. . . ." 927 F.Supp. at 846. Our description of the accident is taken from defense exhibits. Plaintiffs have not offered an explanation of how the accident occurred, and have focused instead on the biological damage they allege it caused. Nevertheless, a basic understanding of the defendant's theory of how the accident occurred provides helpful background to a Daubert analysis of the disputed expert testimony plaintiffs attempted to offer. It is in this context only that we set forth a description of the accident. We caution, however, that the description we set forth is intended only for the limited purpose of framing our Daubert discussion. It is not intended to suggest the appropriate resolution of any factual dispute that may linger as to the precise manner in which the numerous controls all failed at TMI.

74. Prior to the TMI-2 accident, there were "major" reactor accidents at the National Reactor Testing Laboratory in Idaho in

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28, 1979, The Comptroller General Report to the Congress, Three Mile Island: The Most Studied Nuclear Accident in History 1 (1980). Ironically, the "nation's worst nuclear accident" grew out of a minor malfunction, or transient that occurred in the nonnuclear part of the system. NUREG/CR-1250 at 3. For some reason, several feedwater pumps,[75] that normally drew heat from the PWR's cooling water, shut-off automatically.[76] Id. at 310. The system was designed so that when the feedwater pumps tripped, the main turbine and electrical generator also tripped. Id. Thus, by design, the turbine and generator tripped approximately one second later. Id. Three seconds after the turbine tripped, the pressure in the reactor coolant system increased to a level that caused

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1955 and 1961, at the Fermi Reactor in Detroit, Michigan in 1966 and at Browns Ferry 1 in Alabama in 1975. BODANSKY, at 212-13. Major accidents outside of the United States occurred at Chalk River, Canada in 1952, Windscale, England in 1957, Lucens, Switzerland in 1969 and, perhaps the most famous of all reactor accidents, at Chernobyl, in Ukraine about 30 miles south of the border with Belarus, (both of which were then part of the former USSR) in 1986. Id.

75. Neither the condensate nor the feedwater systems are unique to nuclear power plants. Both systems are similar to those used in fossil-fuel plants. NUREG/CR-1250 at 310.

76. The exact reason why the water pumps tripped has not been determined. NUREG/CR-1250 at 311. However, it has been postulated that the operations of a condensate polisher in the auxiliary building was implicated in the tripping of a condensate pump which in turn caused the tripping of the main feed water pumps. NUREG/CR-1250 at 310-311.

the PORV to open in order to release the pressure. Id. When the PORV opened, the fission process in the reactor core automatically shut down. Id. Consequently, the heat generation in the reactor core dropped to decay heat levels. J.A. Daniel, Noble Gas Transport at 5.

However, the PORV did not close as it should have when the system pressure was reduced to acceptable levels. Instead, it remained open for approximately 2 hours. Comptroller General Report ("CGR") at 2. Unfortunately, the personnel operating Unit 2 did not realize that the PORV had not closed. They believed that it had automatically closed when the system was depressurized. Id.; NUREG/CR-1250 at 324. Because the PORV remained open, reactor coolant water flowed from the reactor coolant system into the reactor coolant drain tank, which is designed to collect reactor coolant that is released from the reactor coolant system through the PORV during power operation. Daniel, Noble Gas Transport at 6. The continued flow of reactor coolant water into the reactor coolant drain tank caused a safety valve to lift on the drain tank and a drain tank rupture disk to burst. Id. This rupture disk burst allowed the reactor coolant water to be discharged directly into the reactor building, which overfilled along with its sump pumps. Id. The reactor building sump pumps were on automatic and aligned with the auxiliary building sump tank. Id. at 31. When the reactor building sump pumps overfilled, some coolant water was transferred to the aligned auxiliary building sump tank. Id. For some reason, there was no rupture disk on the sump tank and reactor coolant water was discharged directly into the auxiliary building. Id. at 31; CGR at 2. The contaminated coolant water continued to flow from the reactor building

into the auxiliary building for several days. CGR at 2. Estimates of the amount of radioactive water discharged into the reactor and auxiliary buildings range from 700,000 gallons, Nuclear Energy Institute, The TMI 2 Accident: Its Impact, Its Lessons, <http://www.nei.org/pressrm/facts/TMI-2.htm>, to 5,000,000 gallons. NUREG/CR-1250 at 339.

Approximately 2 minutes into the accident, the emergency core cooling system ("ECCS") began pumping water into the reactor core. CGR at 2. However, operations personnel, still believing that the PORV had closed, and therefore unaware that reactor coolant water was escaping from the reactor coolant system, turned off most of the water flowing to the core through the ECCS. Id. They did so believing that they were preventing the reactor system from becoming filled with water — a condition they were required to prevent. Id.

However, there was not enough coolant water being circulated through the reactor coolant system to cool the reactor core because reactor coolant water was being discharged into the reactor building. Consequently, the core reaction was producing more heat than the coolant system was removing, and the core began to heat up. Daniel, Noble Gas Transport at 6. The loss of reactor coolant water allowed the reactor core to become uncovered. Id. Within three hours of the beginning of the accident, as much as two-thirds of the twelve-foot high core was uncovered. Temperatures reached as high as 3500 to 4000 degrees Fahrenheit or more in parts of the core during its maximum exposure. THE REPORT OF THE PRESIDENT'S COMMISSION ON THE ACCIDENT AT THREE MILE ISLAND, THE NEED FOR

Appendix A

CHANGE: THE LEGACY OF TMI 100 (1979) (THE KEMMENY REPORT).

About 2-1/2 hours into the accident, some of the fuel rods in the reactor cracked, releasing xenon and other fission product gases, which had accumulated in the fuel rod gap between the fuel and the cladding, into the coolant water. Daniel Aff. at ¶28. Over the next few hours, more fuel rods cracked, releasing radioactive iodine and cesium into the primary coolant water as well as additional noble gases. Id.

A series of events then unfolded involving various reactions, valves and controls. The end result was that, nearly 10 hours into the accident, there was a sudden spike of pressure and temperature in the reactor building. Id. at 329. Initially, the spike was dismissed as some type of instrument malfunction. Id. at 330. However, operations personnel learned on March 29th that the spike was caused by the explosion of hydrogen gas in the reactor building. Id. at 329; CGR at 2. Fears of another hydrogen explosion developed when a hydrogen gas bubble was later found in the reactor system. CGR at 2; NUREG/CR-1250 at 336, 338. Presumably, there was a concern that another hydrogen explosion would damage the reactor vessel, leading to further releases of radioactive material. NUREG/CR-1250 at 338. However, the fears about another hydrogen explosion were later learned to be unfounded. Id.; CGR at 2.

During the last days of March and the first week of April, operations personnel began to regain control and contain the radioactive releases caused by the accident. See NUREG/CR-1250 at 334-39. However, it was not until the afternoon

on April 27, 1979 that stable conditions were finally established in TMI-2. Id. at 339.

B. Radioactive Materials Released to the Environment.

The parties generally agree that the radioactive fission products released to the environment as a result of the accident escaped from the damaged fuel and were transported in the coolant through the letdown line into the auxiliary building. NUREG/CR-1250 at 343; Daniel, Noble Gas Transport at 33 ("The major pathway for fission product transport to the auxiliary building was through the let down piping of the makeup and purification system."); Daniel Aff. at ¶22. Once in the auxiliary building, the radioactive fission products were released into the environment through the building's ventilation system.[77] NUREG/CR-1250 at 343; Daniel, Noble Gas Transport at 60. Because of the volatility of noble gases and radioiodines, those elements were the

77. TMI-2 also contained a treatment system, called the "liquid radio waste treatment system", which was designed to collect, process, monitor and recycle or dispose of radioactive liquid wastes prior to discharge to the environment. After the system processed the liquid radwaste, it was discharged into the Susquechanna River. However, because the primary coolant water flowed into the auxiliary building during the accident, the liquid radwaste treatment system was overwhelmed and radioactive materials were released to the Susquechanna River. The Nuclear Regulatory Commission's Special Inquiry Group concluded that the quantity of radioactive materials contained in the liquid released into the Susquechanna River was not significant. NUREG/CR-1250, at 347-51. None of the plaintiffs here claim harm as a result of the releases of liquid radwaste into the river.

primary radionuclides available for release from the auxiliary building. NUREG/CR-1250 at 343. Two krypton isotopes, 87 and 85, were not released in significant quantities because of the short half-life of 87Kr and because of the small amount of 85Kr in the reactor core. Id. Nonetheless, despite the various filters, radioiodines were released.[78] After the first day, the quantities of 88Kr and 135Xe were reduced by radioactive decay. Id. All of the 133I contained in the coolant which was released to the auxiliary building eventually decayed to 133Xe and 133mXe. Id. These radionuclides were the predominate ones released from the plant to the environment. Id. at 344; Daniel Aff. at ¶35.

C. Pathways of Exposure to Radioactive Materials.

The various mechanisms of human exposure to radioactive materials after such materials have been released into the environment are called "pathways". NATIONAL RESEARCH COUNCIL, RADIATION DOSE RECONSTRUCTION FOR EPIDEMIOLOGIC USES 28 (1995) (hereinafter "RADIATION DOSE RECONSTRUCTION"). The pathways are "qualitatively well-known and their relative importance is understood." CHERNOBYL, at 31. Generally, when radioactive materials from nuclear power plants are released into the atmosphere, they are released into a region called the "planetary boundary layer." This is an area between the surface of the ground and an elevation of 100 meters. RADIATION DOSE RECONSTRUCTION, at 28. Once the radioactive material

78. They included, 131I, 133I and 135I, because of their abundance in the coolant and the length of their half-life. Id.

is released, turbulence in the atmosphere mixes the effluent particles and gases within the resulting contaminated cloud or "plume" and the plume is transported downwind. Id. The mixing of the radioactive particles and the transport of the resulting plume are called "dispersion". Id.

Obviously, the extent and direction of a dispersion depends on many factors including wind direction, wind speed and weather, as well as the heat content of the plume, and the characteristics of a given terrain over which the plume may be carried. CHERNOBYL, at 32. As the radioactive cloud is dispersed and transported by prevailing winds, exposure to the radionuclides first occurs through external and internal irradiation. Id., at 31; RADIATION_DOSE RECONSTRUCTION, at 29. The contents of the plume are depleted over time as the radionuclides settle to the ground in response to gravitational forces ("dry deposition") of through precipitation or combination with airborne moisture such as fog (wet deposition). CHERNOBYL, at 31-32. However, as suggested by some of our discussion above, exposure can continue by external irradiation from deposits of radioactive material, inhalation of any materials suspended in the atmosphere, or transfer of the radioactive material through the terrestrial and aquatic environment to food and water, and then to internal irradiation. Id.

VI. LEGAL DISCUSSION

With the foregoing discussion in mind, we are ready to begin our discussion of the District Court's evidentiary rulings. The Daubert challenge to the plaintiffs' experts implicates the reliability of the expert testimony that

plaintiffs sought to admit into evidence. We now begin our analysis of that testimony, the issues of causation and the scientific principles implicated by the plaintiffs' attempt to establish the requisite nexus between the accident at TMI-2 and their injuries.

A. The Trial Plaintiffs' Appeal.

1. Background.

The 10 Trial Plaintiffs claim that their diseases, or the fatal diseases of the decedents whose claim their personal representatives assert, were caused by the radioactive materials released into the environment as result of the TMI-2 accident. More specifically, they allege their conditions were caused by gamma (g) ray exposure from radioactive iodine, xenon and krypton. In re TMI Litigation Consolidated Proceedings, 927 F.Supp. 834, 840 (M.D.Pa.1996) (the "Summary Judgment Opinion").

We have previously held that plaintiffs seeking to recover for injuries allegedly caused by TMI-2 must show that: (1) the defendants released radiation into the environment in excess of the levels permitted by federal regulations in effect in 1979, i.e., 0.5 rems (500 mrems) or 5 mSv; (2) the plaintiffs were exposed to this radiation (although not necessarily at levels prohibited by those regulations); (3) the plaintiffs have injuries; and (4) radiation was the cause of those injuries. See In re TMI, 67 F.3d 1103, 1119 (3d Cir.1995), cert. denied, 516 U.S. 1154, 116 S.Ct. 1034, 134 L.Ed.2d 111 (1996). We have also held that the

"exposure element requires that plaintiffs demonstrate they have been exposed to a greater extent than anyone else, i.e., that their exposure levels exceeded the normal background level." Id. (citation and internal quotations omitted).

Throughout this litigation, the defendants have conceded that radioactive materials were released into the environment, and that the releases at the plant boundaries exceeded 0.5 rem (500 mrem). However, they claim that no plaintiff was in an area where he or she could have been exposed to dose in excess of 0.5 rem. In re TMI, 67 F.3d at 1109. Appellees point to a number of studies undertaken by governmental entities in the years immediately following the TMI-2 accident. The Nuclear Regulatory Commission ("NRC"), the Department of Energy ("DOE"), the Environmental Protection Agency ("EPA"), the Department of Health, Education and Welfare ("HEW"), a special President's Commission (the "Kemmeny Commission"), a special NRC investigation (the "Rogovin Report"), and the Pennsylvania Department of Health, all studied various aspects of the accident. Appellees' Br. at 3-4. The government entities studied the time line of events recorded by in-plant computers and strip charts during the accident to determine what was happening minute by minute. Id. at 4. The inquiry examined the records from monitors located in several locations inside the plant including the ventilation stack through which the radioactive releases occurred. Off site monitors at multiple locations where either the utility operating the plant or the Commonwealth of Pennsylvania had instruments collecting and recording data on doses in the communities surrounding Three Mile Island were also

studied.[79] Id. The governmental entities also collected and assessed thousands of environmental samples of milk, water, soil, vegetation, and food. Id. They made whole body counters available at no charge to the public, and over seven hundred people were scanned to see if they had any radionuclides in their bodies from the accident. Id. Local hospitals provided free thyroid scans to anyone interested, and hundreds of people took advantage of these scans to discover any radioactive iodine that might have accumulated in their thyroids. Id. The DOE also conducted an extensive examination of the damaged reactor core in an attempt to quantify the amount of fission products remaining so as to better calculate the quantity that was released into the environment. Id.

Defendants insist that all of these studies consistently concluded that the accident released something less than nine million curies of the noble gases, xenon and krypton, and radioactive iodine resulting in exposures of no more that

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79. Instruments used to measure airborne radiation, known as thermoluminescent dosimeters ("TLDs"), were used by the utility, Metropolitan Edison, and by the Commonwealth to monitor radiation in the surrounding communities in a program known as the TMI Radiation Environmental Monitoring Program ("REMP"). Summary Judgment Opinion, 927 F.Supp. at 848. According to the NRC's Special Inquiry Group, "TLDs provide the best estimate of the integrated radiation dose at a specific location. . . ." NUREG/CR-1250, at 358. A TLD consists of "[a] material, generally a salt such as lithium-fluoride, which can store energy absorbed from nuclear radiation. This stored energy is later released from the [material] by heating and evaluated electronically to give information about the total radiation dose." President's Commission, Report of the Task Group on Health Physics and Dosimetry 39 (1979).

100 mrem in the immediate vicinity of the plant, and dropping quickly to tens or just a few millirems within a few miles of the plant. Id. at 5. For example, the NRC Special Inquiry Group Report concluded that the radioactive releases resulted in an average equivalent dose of 1.4 mrem to the approximately two million people living in the area. NUREG/CR-1250 at 153. Defendants contend that these studies conclusively demonstrate that the accident did not cause in releases of radionuclides in sufficient amount to pose a significant threat to the health of the people living around Three Mile Island. Appellees' Br. at 5. For example, the Ad Hoc Population Dose Assessment Group[80] concluded that the predominant exposure to people outside the plant boundaries occurred in the north-northwest sectors, the east-northeast sectors and the south-southeast sectors, with the east-north east sector registering the highest cumulative dose of 83 mrem. AD HOC POPULATION DOSE ASSESSMENT GROUP, POPULATION DOSE AND HEALTH IMPACT OF THE ACCIDENT AT THE THREE MILE ISLAND NUCLEAR STATION 44 (1979). The Ad Hoc Group also concluded the following regarding the potential health effects on the population living around Three Mile Island:

> The projected total number of fatal cancers is less than 1 (0.7). The additional number of non-fatal cancers in also less than 1 (0.7). The additional number of genetic effects for all generations is

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80. The Ad Hoc Group was composed of representatives of the Nuclear Regulatory Commission, the Environmental Protection Agency, and the Department of Health, Education and Welfare (now the Department of Health and Human Services).

> also less than 1 (0.7). . . . All of these values are small compared to either the existing annual incidence of similar effects or the potential effects estimated to result from the natural background radiation. . . . Comparing the total potential health impact of the accident with the estimated lifetime natural risk indicates that these effects, if they were to occur, would not be discernible. The uncertainties in the risk from low-level ionizing radiation would not alter this conclusion.

Id. at 60.

As the years passed and health concerns about the accident persisted, the Commonwealth of Pennsylvania's Department of Health conducted several epidemiological[81] studies of the community surrounding Three Mile Island.[82]

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81. Epidemiology is the "study of the distribution and determinants of health-related states and events in populations and the application of this study to control of health problems." FEDERAL JUDICIAL CENTER, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 174 (1994). "Epidemiology is concerned with the incidence of disease in populations and does not address the question of the cause of an individual's disease." Id. at 167.

82. The studies are: Bratz, J.R., et al., Three Mile Island (TMI) Pregnancy Outcome Study-Final Report (1988); Tokuhata, George K., et al., Cancer Mortality and Morbidity Incidence Around TMI, Division of Epidemiological Research, PA Department of Health, (1985); Digon, E., et al., Infant, Fetal Neonatal and Perinatal Mortalities in the Three Mile Island Area, (1988); Ramasway, K., et al., Three Mile Island (TMI) Population Registry-Based Cohort Mortality: 1979-1985 Period, (1988).

The Department of Health examined pregnancy outcomes, cancer incidence and cancer mortality in the Three Mile Island area and compared them with state and national norms. The Department's studies concluded there were no significant differences between the studied groups and the state and national norms. Appellees' Br. at 5. The defendants believe that these epidemiological studies further support their claim that the radionuclides released by the accident did not pose any significant health risks.

However, the Trial Plaintiffs rely, in part, on a report of the TMI Public Health Fund,[83] which opined, inter alia, that the aforementioned studies were seriously flawed insofar as they attempted to calculate dose exposures to the individuals in the communities surrounding Three Mile Island. See THREE MILE ISLAND PUBLIC HEALTH FUND, A REVIEW OF DOSE ASSESSMENTS AT THREE MILE ISLAND AND RECOMMENDATIONS FOR FUTURE RESEARCH, APPENDIX A 1 (1984). Plaintiffs gathered their own experts to conduct many of the tests recommended

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83. The Three Mile Island Public Health Fund was established as part of the settlement of a class action for economic losses attributable to the TMI-2 accident. The plaintiffs there consisted of three separate classes — one class consisted of businesses which suffered economic loss, one class consisted of individuals who suffered economic loss and one class consisted of individuals who sought medical detection services allegedly needed because of the accident. Under the settlement, a $25 million fund was established, with $20 million available to pay the claims of the businesses and individuals in the first two classes and $5 million set aside for the Public Health Fund, the purpose of which was to, inter alia, "finance studies of the long term health effects of the TMI incident." In re Three Mile Island Litigation, 557 F.Supp. 96, 97 (M.D.Pa.1982).

by the TMI Public Health Fund in its report. Appellants' Br. at 11. The scientific team that the Trial Plaintiffs assembled focused on "biological indicators of radiation dose." Trial Plaintiffs contend that those biological indicators constitute a "body of evidence . . . greatly overlooked or ignored in early studies. . . ." Id. at 12. According to the Trial Plaintiffs, the biological indicators of radiation dose conclusively demonstrate that area residents were exposed to an equivalent dose of over 100 rem or 1 Sv. Summary Judgment Opinion, 927 F.Supp. at 848. Perhaps because of their faith in the reliability of these biological indicators, Trial Plaintiffs proceeded to try their respective claims on the theory that each of the Trial Plaintiffs had been exposed to an equivalent dose of at least 10 rem or 100 mSv each.[84] See Brief of Non-Trial Plaintiffs (No. 96-7624), at 18, 38.

To support their contention that they were each exposed to significantly higher doses of ionizing radiation than the governmental studies calculated, and the defendants admit to, the Trial Plaintiffs developed a "blowout" theory. Under that theory, one or more unfiltered hydrogen blowouts occurred on the afternoon of the first day of the accident, whereby large quantities of radioactive noble gases and other

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84. In contrast, the appellees' expert calculated that only one of the Trial Plaintiffs was exposed to a dose greater than 25 mrem. She is Jolene Peterson, who appellants claim was exposed to an maximum dose of 75 mrem. Appellees' expert further calculated that plaintiffs Pearl Hickernell, Ethelda Hilt, Leo Beam and Ronald Ward, were exposed to maximum doses under 10 mrem and that plaintiffs Garry Villella, Lori Dolan, Joseph Gaughan and Paula Obercash were exposed to maximum doses between 15 and 25 mrem. Summary Judgment Opinion, 927 F.Supp. at 852.

radioactive nuclides, such as iodine and cesium, were expelled into the environment. Summary Judgment Opinion, 927 F.Supp. at 857. They assert that, after the blowout, an extremely dense, yet narrow, plume of radioactive effluents traveled through the atmosphere evading all of the radiation monitors in place in the areas surrounding the plant and the communities. Id.

The "blowout" theory was first developed by Trial Plaintiffs' expert, Richard Webb, who opined in a report that a total of 106 million curies of noble gases were released during the accident, more than half of which escaped during a two and one-half hour "blowout" on the afternoon of the first day of the accident. Webb did not testify at the in limine Daubert hearing. After the first round of hearings ended, Webb left a voice-mail message for defendants' counsel recanting his proposed testimony. The District Court concluded that Webb's recantation only confirmed its intention to exclude Webb's proffered testimony as unreliable.[85] In re TMI Litigation Cases Consolidated II, 911 F.Supp. 775, 791 (M.D.Pa.1996).

However, because of the significance of the "blowout" theory to plaintiffs' case, the District Court did permit the Trial Plaintiffs to use another witness — a nuclear engineer named David Lochbaum — to replace Webb's testimony about a blowout. Lochbaum testified at an in limine hearing that significantly more than 10 million curies of noble gases reached the environment as a result of the accident. He opined

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85. The Trial Plaintiffs do not argue that Webb's report and testimony should have been admitted.

that these gases were released from steam generator B in the early hours of the accident. However, somewhat contradictory, he also testified that he "did not believe that there was evidence of a blowout." In re TMI Litigation Cases Consolidated II, 922 F.Supp. 997 (M.D.Pa.1996). He testified, however, that if a blowout did occur, it was of limited length — on the order of minutes and not over the two or three hours Webb believed. Id. Nonetheless, he testified that the blowout did release significant amounts of noble gases even though it lasted only a short time. Id.

The District Court concluded that Lochbaum's testimony was dependent upon other of the Trial Plaintiffs' experts being able to demonstrate that significant amounts of radionuclides were emitted. The court reasoned that if other experts were able to competently testify about significant amounts of noble gases being emitted, then Lochbaum's testimony was admissible on the issue of the source of the emissions. Thus, the court concluded that if no other expert could competently testify about significant releases of radionuclides, Lochbaum's proffered testimony about a blowout must be excluded. Id. Consequently, the trial plaintiffs proffered several witnesses whose testimony was relevant to the existence of a blowout. It is those witnesses for the most part, whose testimony was challenged under Daubert, and whose reliability is now at issue.

With this background established, the stage is properly set to begin our analysis of the District Court's Daubert decisions regarding the Trial Plaintiffs' dose exposure experts.

2. Standards Governing the Admissibility of Scientific Evidence.

Federal Rule of Evidence 702 provides that:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

In Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993), the Court set forth parameters for determining when proffered expert testimony can be admitted into evidence.[86] The Court held

> an inference or assertion must be derived by the scientific method. Proposed testimony must be supported by appropriate validation — i.e., "good grounds," based on what is known. In short, the requirement that an expert's testimony pertaining to "scientific knowledge" establishes a standard of evidentiary reliability.

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86. In Daubert, the Court also held that Fed.R.Evid. 702 does not incorporate the common law rule, known as the "Frye rule". See Frye v. United States, 54 App.D.C. 46, 293 F. 1013, 1014 (1923). In Frye, the court held that expert testimony is admissible only insofar as it is based on a technique that is "generally accepted" in the scientific community.

Id. at 590, 113 S.Ct. 2786.[87] Rule 702 also requires that the evidence or testimony "assist the trier of fact to understand the evidence or to determine a fact in issue." "This condition goes primarily to relevance." Id. at 591, 113 S.Ct. 2786. This "consideration has been aptly described . . . as one of 'fit' ". Id. Rule 702's " 'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility." Id. at 591-92, 113 S.Ct. 2786.

The Court in Daubert concluded that Rule 702 "clearly contemplates some degree of regulation of the subjects about which an expert may testify." Id. at 589, 113 S.Ct. 2786. Thus, the Court established a "gatekeeping role for the judge." Id. at 597, 113 S.Ct. 2786. The Court wrote:

> Faced with a proffer of expert scientific testimony, . . . the trial judge must determine at the outset, pursuant to Rule 104(a),[88] whether the expert is

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87. Daubert concerned the admissibility of scientific evidence proffered by plaintiffs that demonstrated that the prescription anti-nausea drug, Bendectin, marketed by defendant and ingested by pregnant women, caused birth defects. Because the issue in Daubert was scientific knowledge, the Court did not discuss "technical or other specialized knowledge" to which Rule 702 also applies. Daubert, 509 U.S. at 590 n. 8, 113 S.Ct. 2786. Recently, however, the Supreme Court has decided that Daubert applies not just to testimony based on "scientific" knowledge, but also to "technical or other specialized knowledge." Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999).

88. Fed.R.Evid. 104(a) provides: "Preliminary questions concerning the qualification of a person to be a witness, the existence of a privilege, or the admissibility of evidence shall be determined by the court, subject to the provisions of subsection (b) [pertaining to conditional admissions]."

> proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue. This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.

Id. at 592-93, 113 S.Ct. 2786. The Court held that these matters should be established "by a preponderance of proof," Id. at 593 n. 10, 113 S.Ct. 2786, and identified some "general observations," relevant to the proponent's burden, while acknowledging that the factors it identified were not all-inclusive. Id. ("[m]any factors will bear on the inquiry.").

First, "a key question to be answered in determining whether a theory or technique is scientific knowledge that will assist the trier of fact will be whether it can be (and has been) tested." Id. "Another pertinent consideration is whether the theory or technique has been subjected to peer review and publication." Id. Publication, which is an element of peer review, "is not a sine qua non of admissibility: it does not equate with reliability." Id.

However, submission to the scrutiny of the scientific community is a component of "good science." Id. Accordingly, "[t]he fact of publication (or lack thereof) in a peer reviewed journal . . . will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology upon which an opinion is premised." Id. at 594, 113 S.Ct. 2786. Third, "in

the case of a particular scientific technique, the court ordinarily should consider the known or potential rate of error, and the existence and maintenance of standards controlling the technique's operation." Id. Fourth, and finally, "general acceptance" can have bearing on the inquiry. Id. "Widespread acceptance can be an important factor in ruling particular evidence admissible, and a known technique which has been able to attract only minimal support with the community may properly be viewed with skepticism." Id. However, "general acceptance" is "not a necessary precondition to the admissibility of scientific evidence." Id. at 597, 113 S.Ct. 2786. Indeed, the Court specifically declined to require general acceptance when it rejected the Frye rule. See n. 86 supra. Rather, general acceptance is but one factor that is considered along with all other factors relevant to the 702 inquiry.

The Court concluded by emphasizing that the "inquiry envisioned by Rule 702 is . . . a flexible one," and by reminding the trial courts that the "focus . . . must be solely on principles and methodology, not on the conclusions they generate." Id. at 595, 113 S.Ct. 2786. The Court also noted that the District Court should be mindful of other applicable rules in assessing a proffer of expert scientific testimony under Rule 702. Specifically, Rule 703 which provides that expert opinions based on otherwise inadmissible hearsay are to be admitted only if the facts or data relied upon are of a type reasonably relied upon by experts in the particular field in forming opinions; Rule 706 which allows the court in its discretion to procure the assistance of an expert of its own choosing; and Rule 403 which permits the exclusion of relevant evidence if its probative value is substantially

outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury. Id.

We applied the teachings of Daubert in deciding In re Paoli Railroad Yard PCB Litigation, 35 F.3d 717 (3d Cir.1994), cert. denied, 513 U.S. 1190, 115 S.Ct. 1253, 131 L.Ed.2d 134 (1995) (hereinafter "Paoli II"). There, we held that Rule 702 has two major requirements. First of all, the proffered "expert" must be qualified to express an expert opinion. This "qualifications" requirement is liberally interpreted and includes "a broad range of knowledge, skills, and training," Paoli II, at 741.[89] However, "the level of expertise may affect the reliability of the expert's opinion." Id.

Secondly, the proffered expert opinion must be reliable. Thus, "an expert's testimony is admissible so long as the process or technique [as opposed to the conclusion] the expert used in formulating the opinion is reliable." Id. at 742 (emphasis added). We listed various factors enunciated in Daubert that assist in evaluating whether a given scientific methodology is reliable, and we also relied upon several factors we had previously identified in United States v. Downing, 753 F.2d 1224 (3d Cir.1985). Paoli II, at 742. We held that the District Court's inquiry under Rule 702 should be guided by the criteria set forth in Daubert and Downing as well as other factors that may be relevant to a given inquiry. The factors we specifically identified include:

> "(1) whether a method consists of a testable hypothesis; (2) whether the method has been

89. The liberal policy of admissibility under Rule 702 extends to the substantive as well as the formal qualification of experts.

> subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put."

Paoli II, at 742 n. 8. We also noted that the proffered expert testimony must assist the trier of fact. In other words, admissibility depends in part on "the proffered connection between the scientific research or test result to be presented and particular disputed factual issues in the case." Id. at 743.

Furthermore, we cautioned that the standard for determining reliability "is not that high," Id. at 745, even given the evidentiary gauntlet facing the proponent of expert testimony under Rule 702. Thus, plaintiffs do not "have to prove their case twice — they do not have to demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are correct, they only have to demonstrate by a preponderance of evidence that their opinions are reliable."[90] Id. at 744. In other words, "the evidentiary requirement of reliability is lower than the merits standard of correctness." Id.

> "The grounds for the expert's opinion merely have to be good, they do not have to be perfect. The

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90. The distinction is indeed significant as it preserves the fact finding role of the jury.

> judge might think that there are good grounds for an expert's conclusion even if the judge thinks that there are better grounds for some alternative conclusion, and even if the judge thinks that a scientist's methodology has some flaws such that if they had been corrected, the scientist would have reached a different result."

Id. Thus, in Paoli II we explained

> the primary limitation on the judge's admissibility determinations is that the judge should not exclude evidence simply because he or she thinks that there is a flaw in the expert's investigative process which renders the expert's conclusions incorrect. The judge should only exclude the evidence if the flaw is large enough that the expert lacks the "good grounds" for his or her conclusions.

Id. at 746.[91]

The test of admissibility is not whether a particular scientific opinion has the best foundation, or even whether the opinion is supported by the best methodology or unassailable research. Rather, the test is whether the "particular opinion is based on valid reasoning and reliable methodology." Kannankeril v. Terminix International Inc., 128 F.3d 802, 806 (3d Cir.1997) (emphasis added). The

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91. Such a flaw undermines the fact finding role of the jury by allowing it to reach factual conclusions which may be based on "unreliable" evidence and, therefore, are more likely to be erroneous.

admissibility inquiry thus focuses on principles and methodology, not on the conclusions generated by the principles and methodology. Id. (citing Paoli II at 744). The goal is reliability, not certainty. Once admissibility has been determined, then it is for the trier of fact to determine the credibility of the expert witness. Id. (citing Paoli II at 743-746). "The analysis of the conclusions themselves is for the trier of fact when the expert is subjected to cross-examination." Id. Therefore, if the methodology and reasoning are sufficiently reliable to allow the fact finder to consider the expert's opinion, it is that trier of fact that must assess the expert's conclusions. The inquiry is a factual one, not a legal one.

Nonetheless, "conclusions and methodology are not entirely distinct from one another." General Electric Co. v. Joiner, 522 U.S. 136, 118 S.Ct. 512, 519, 139 L.Ed.2d 508 (1997). The court "must examine the expert's conclusions in order to determine whether they could reliably flow from the facts known to the expert and the methodology used." Heller v. Shaw Industries, Inc., 167 F.3d 146, 153 (3d Cir.1999). "A court may conclude that there is simply too great a gap between the data and the opinion proffered." Joiner, at 519. However, such an opinion will be excluded not because it is necessarily incorrect, but because it is not sufficiently reliable and therefore too likely to lead the factfinder to an erroneous conclusion.

Here, the District Court assessed the disputed expert testimony under Rule 702 and held that it did not meet the conditions precedent to admissibility under Daubert. We subject the District Court's interpretation of Rule 702 to

plenary review. Paoli II at 749. However, we review the District Court's decision to admit or exclude scientific evidence for an abuse of discretion. Joiner, at 519.[92] An abuse of discretion arises when the District Court's decision "rests upon a clearly erroneous finding of fact, an errant conclusion of law or an improper application of law to fact." Hanover Potato Products, Inc. v. Shalala, 989 F.2d 123, 127 (3d Cir.1993). An abuse of discretion can also occur "when no reasonable person would adopt the district court's view." Id. However, we do not interfere with the District Court's exercise of discretion "unless there is a definite and firm conviction that the court below committed a clear error of judgment in the conclusion it reached upon a weighing of the relevant factors." Id.

With the parameters of our inquiry in mind, the teachings of Daubert and the aforementioned scientific principles as our guideposts, we can now proceed to apply the yardstick of Daubert to the expert opinions at issue here and determine if they were properly excluded under the Rules of Evidence.

3. Trial Plaintiffs' Dose Exposure Expert Witnesses.

i. Ignaz Vergeiner.

a. Qualifications.

Ignaz Vergeiner is a meteorologist with undergraduate degrees in mathematics and physics, and a Ph.D. in

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92. In Joiner, the Court rejected the view that a district court's decision on the admissibility of scientific evidence should be reviewed under a heightened or stringent abuse of discretion standard. That view is the one we adopted in Paoli II at 749-50.

meteorology; all of which were earned at the University of Innsbruck in Austria. He is an Associate Professor in the Department of Meteorology and Geophysics at the University of Innsbruck and has taught graduate and undergraduate courses at that University for twenty years. App. Vol. V., at 3578. He was proffered as an expert in boundary level meteorology in alpine regions.[93] His testimony was offered to explain how the hypothesized plume containing the highly radioactive release that is part of "blow out," traveled and dispersed throughout the area surrounding Three Mile Island.

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93. During his testimony, Vergeiner offered the following definition of "boundary layer meteorology": "Meteorology would be the scientific description of processes occurring in the layer of air between the earth's surface, land or ocean, an up to 10 miles, 20 miles, 50 miles, depending on your discipline; even further, if you wish. But mainly it's the lower 10 miles, 15 miles. And boundary layer meteorology would be the same, but restricted to the layer of air adjacent to the surface, which may be a few hundred meters up to a couple of miles. And boundary layer meteorology, the characteristic is that you work near the earth's surface, which means you have friction and you have the influence of heat input at the earth's surface. Now, for example, this means that the winds change with height in the boundary layer much more than they do in the upper part of the atmosphere. Then you would have the daily range of temperature, warming and cooling, which would be mainly restricted to the boundary layer. And you would have one characteristic, you might have turbulence. You don't always have turbulence, but the boundary layer is a place where you typically may find turbulence." App. Vol. V., at 3999-4000. Vergeiner also testified that the land surrounding Three Mile Island consisted of alpine or mountain terrain. For meteorological purposes, a mountain is a structure that is elevated 50 meters or more above the flat terrain. Id. at 4006-07, 4081-82.

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b. Vergeiner's Opinion.

Vergeiner's proffered testimony covered three areas. First, as an expert in boundary level meteorology, he sought to testify about the weather conditions at Three Mile Island and the surrounding areas during, and immediately following, the accident. He was to testify about his plume dispersion hypothesis based upon his studies of the weather conditions. Secondly, he sought to estimate radiation doses in certain areas surrounding Three Mile Island. Finally, he sought to testify about his distrust and skepticism of the original plant data from TMI-2 concerning plume dispersion and radiation releases in an effort to counter the defendants' evidence regarding exposure.

Essentially, Vergeiner opined that a weather inversion, in combination with the alpine terrain that surrounds Three Mile Island, prevented the radioactive plume from rising high into the atmosphere, spreading out and dispersing in the expected "Gaussian" manner.[94] App. Vol. V., at 4005-09. Instead, he believed that the radioactive plume remained narrow, concentrated and intense and moved erratically in a north, northwest direction from Three Mile Island. He believed that it frequently came in contact with hilly terrain which caused it to reconcentrate, and that after it reconcentrated, it touched down on the ground and exposed the population to high levels of radiation. Id. at 3583-85;

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94. Under the "Gaussian plume model", dispersion is three-dimensional, i.e., dispersion will be downwind, cross-wind and vertical. See Environmental Software and Services, AirWare: Urban Air Quality Assessment and Management (visited January 4, 1999) <http://www.ess.co.at/AIRWARE/gauss.html>.

3761-68; 4017-29. To illustrate his plume dispersion theory, Vergeiner produced a water model and a "plume movie". The latter is not a "movie" at all, but is rather a series of sketches he drew by which he illustrated the plume movement he hypothesized. Id. at 3769-775; 4076-78. The water model is a video of a large scale model he built in which colored water was injected into a tank filed with clear water that contained a model of alpine terrain. Id. at 3756-60.

Vergeiner's qualifications as an expert in meteorology were not in dispute. Nonetheless, the defendants moved to exclude all of his proffered testimony under Rule 702. After a hearing, the District Court subjected his proffered testimony to an exhaustive and rigorous Daubert/Paoli II analysis and excluded the majority of it, including the plume movie and the water model. In re TMI Litigation Cases Consolidated II, 911 F.Supp. 775, 791-799 (M.D.Pa.1996). However, the court held that, as an expert in meteorology, Vergeiner could testify about the weather conditions during and immediately following the accident if the Trial Plaintiffs could demonstrate how that testimony would assist the jury in determining a pertinent fact. Id. at 799.

c. Discussion and Conclusions.

The Trial Plaintiffs argue that by excluding the overwhelming majority of Vergeiner's proposed testimony, the District Court "elevate[d] its opinion of science over that of Dr. Vergeiner's, even though the court had no training in the complex meteorological issues that he discussed. . . ." Trial Plaintiffs' Br. at 24. We disagree. Preliminarily, we note that a proponent of rejected expert testimony could

always level such a challenge against an unfavorable Daubert ruling. However, an adverse ruling under Daubert does not, in and of itself, suggest that a court substituted its opinion for that of a trained scientist. Here, we conclude that the trial court did not substitute its scientific opinion for Vergeiner's. Rather, the court correctly applied the Daubert/Paoli II guidelines and properly found the bulk of Vergeiner's testimony "unreliable and therefore inadmissible under Rule 702." 911 F.Supp. at 799. Although we find it unnecessary to review the District Court's application of each Daubert/Paoli II criteria, we believe a few examples demonstrate that the District Court's decision to exclude the bulk of Vergeiner's proposed testimony was not an abuse of discretion.

First, in formulating his plume dispersion hypothesis, Vergeiner discarded standard and generally accepted computer models, especially the Gaussian plume model.[95] App. Vol. V, at 4003-07. At the hearing, Vergeiner testified that the Gaussian plume model was not an adequate model to hypothesize plume dispersion given the weather conditions on the day of the accident, and considering the terrain surrounding Three Mile Island. Id. at 4007; 4051-54. In rejecting the standard computer models, Vergeiner wrote in one of his two reports:

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95. The Gaussian plume model was the model used by appellants' expert, Keith Woodward, to formulate his opinion as to the atmospheric dispersion of the radioactive materials released as a result of the accident. See Affidavit of Keith Woodard, at ¶14. However, by referring to the Gaussian plume model, we do not mean to suggest that it is the model Vergeiner should have used. Rather, it is mentioned only as an example of a generally accepted computer model.

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Clearly, available synoptic meteorological[96] observations cannot determine the flow field and

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96. At the hearing, Vergeiner offered the following definition of "synoptic meteorology."

> Synoptic meteorology is essentially the — comes out of the realization that when you plot weather observations taken at the same time, you know, which could be nighttime in Europe and late afternoon in this country, then you can draw maps. And you start to interpret them and you find out that, you will find certain prominent features, like weather fronts, and they would move in a coordinated way, right? You would get the rains first in, God knows where, in Chicago, and later on you would get them further east. And this is what's called synoptic meteorology.
>
> And to do that, of course, you don't want to look only at surface observations, but you do want to look at upper air observations, because the air moves faster at upper levels. And in order to interpret your features, you do want both surface and upper air observations.
>
> And for upper air, there is a network of balloons soundings, these big balloons with an instrument package, and they are launched every 12 hours at stations like Pittsburgh, New York — Albany, New York, Washington, D.C., stations at about that distance. And from those radio soundings, you get temperature and winds and pressure at upper levels. They are the backbone of synoptic meteorology.

App., Vol. V, at 4033-34. As part of his synoptic meteorological analysis, Vergeiner presumably analyzed "a wide range of

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dispersion characteristics down to a scale of hundreds of meters or a few kilometers, as needed to estimate local transport and diffusion from TMI releases. . . .

So why not straightaway model the flow numerically using the power of modern computers? Let me remind the reader of the enormous complexity of such a task. Transport and dispersion models exist to the hundreds, many of them in the nuclear industry or in the scientific "grey zone" around it. . . .

Quite a few of these models are global in scale, and some apparently have succeeded in simulating the path and contaminating action of the Chernobyl clouds reasonably well, after years of tuning and verification on the many observations available. . . .

Documentation is a problem, as well as the need for special graphics and internal routines, or compatibility of various computer languages. Not all applications have been successes. . . .

(Cont'd)
meteorological data, including national data regarding the movement of weather fronts throughout the country, regional data from the eastern part of the United States, and local data from the TMI area." App. Vol. V, at 3549. The District Court found that synoptic analysis is a standard meteorological technique that has been subjected to significant peer review. 911 F.Supp. at 794-95.

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> It was my judgement, therefore, not only that it did not seem feasible to obtain access and results within a limited time span and financial frame, but that relatively simpler, well-tested, more robust and accessible models might be just as good, even preferable. This may appear to do injustice to the more than 50 man-years' expert work condensed in this enormous structure. There is no doubt that each of these models is capable of computing flow structures very suggestive of real nature, but I couldn't convince myself that the enormously increased expense would bear a sound relation to similarly improved results.

Ignaz Vergeiner, Treatise on the TMI-2 Accident of March 28, 1979, Particularly its Meteorological Aspects Including Transport and Dispersion of the Radionuclides Released 49-50 (July 1994) (unpublished) (hereinafter "Vergeiner I"); App. Vol. V, at 3634-35.

Rather than using the standard computer models, Vergeiner chose to use a "numerical model" which he initially referred to by the acronym "AMBIMET," Vergeiner I, at 51; App. Vol. V, at 3636, but which he later called, in his second report, the "FITNAH model operated by AMBIMET." Ignaz Vergeiner, Treatise on the Meteorological Aspects of the TMI-2 Accident 49 (February 1995) (unpublished) (hereinafter "Vergeiner II"); App. Vol. V, at 3752. In any event, he described the model he used, whether AMBIMET or FITNAH, as "a regional one, not designed to simulate local flows on the scale of hundreds of meters" that "requires proper synoptic input." Vergeiner I, at 51-52; App. Vol. V, at 3636-37.

However, Vergeiner never provided any testimony, documentation or any other evidence that the numerical models he did use are generally accepted within the meteorological or the broader scientific community. Although the "general acceptance" test of Frye v. United States, 54 App.D.C. 46, 293 F. 1013 (1923), was displaced by the Federal Rules of Evidence, Daubert, 509 U.S. at 589, 113 S.Ct. 2786, "general acceptance" in the scientific community can "yet have a bearing on the inquiry," and be an "important factor in ruling particular evidence admissible." Daubert, at 594, 113 S.Ct. 2786. "[A] known technique which has been able to attract only minimal support within the community may properly be viewed with skepticism." Id. (quoting United States v. Downing, 753 F.2d 1224, 1239 (3d Cir.1985)). Thus, while general acceptance is not the focus of the inquiry, it is a relevant factor which may be considered. Accordingly, a court may well cast a jaundiced eye upon a technique which is not supported by any evidence of general acceptance absent other indicia of reliable methodology. Here, it is impossible to know whether the disputed model's methodology can or has been tested or whether the model has been subjected to peer review or publication. Neither can we determine its known or potential rate of error. Consequently, we can hardly conclude that the plume dispersion model Vergeiner hypothesized meets the Daubert requirement of evidentiary reliability.

Second, Vergeiner's "plume movie" (which, as noted earlier, is but rather a series of sketches[97] he drew to illustrate

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97. The plume movie is located in Vergeiner II and is referred to therein as Figure 9.1. Vergeiner II, at 67-71; App. Vol. V, at 3769-74.

his hypothesized plume movements) is based on pure speculation. In his second report, Vergeiner presented his opinion as to behavior of the plume. He wrote:

> For conclusion, I present my own tentative TMI plume "movie" for the first few hours . . . Its chief purpose is visualization of possible plume shifts and exposures, and realization of the kind of information we would need to be reasonably sure about transport and dispersion of TMI-2 effluents. [The plume movie] is the beginning of an investigation, not the end.

App. Vol. V, at 3769 (emphasis added). The speculative nature of the plume movie was made even more apparent during Vergeiner's deposition when he described the plume movie.

> I make it clear that the [plume movie] and following are not meant to be — I think the way I write it is that they are the beginning of a discussion and not the end of a discussion. . . . And I realize it's absolutely clear, and I state it, that this, this is an assumption, I think it's not an unreasonable one, it has some foundation, but at this stage it is just a, well, it's more than a provocation, but this —
>
> Q: It's the articulation of a hypothesis yet to be explored?
>
> A: Of a hypothesis, and it is an illustration, certainly an illustration of winds turning rapidly,

> which they did, that one is for sure, and the consequences of a plume, I wanted to illustrate how distorted a plume can become. I wanted to illustrate the effects. I just don't have enough of a database to prove details of this. This is absolutely clear and conceded. Absolutely clear.

Id. at 3941.

Rule 702 not only requires that the scientific opinion proffered by the expert be supported by "good grounds," Daubert, at 590, 113 S.Ct. 2786, it also mandates that the challenged testimony "assist the trier of fact to understand the evidence or to determine a fact in issue." This requirement is one of relevance and expert evidence which does not relate to an issue in the case is not helpful. Id. at 591, 113 S.Ct. 2786. The expert's testimony must "fit," and admissibility depends, in part, on a connection between the expert opinion offered and the particular disputed factual issues in the case. Paoli II, at 743. "Fit is not always obvious, and scientific validity for one purpose is not necessarily validity for other unrelated purposes." Id. Here, Vergeiner's report and testimony make clear that his plume movie was merely an assumption visualizing possible plume movements. Given its speculative character, the plume movie was properly excluded under Daubert.

We note that in order for expert testimony to be reliable, and therefore admissible, it must be based on the methods and procedures of science rather than subjective belief or speculation. Kannankeril, 128 F.3d at 806 (citing Paoli II, 35 F.3d at 744). Consequently, Vergeiner's plume movie,

and, (as will be discussed), his water model, are also lacking in scientific reliability and are inadmissible because of their speculative character. Nevertheless, we believe that the plume movie and the water model are more appropriately inadmissible because they lack fit.

The water model does not "fit." The water model is a video of a large scale model tank, the bottom of which is a topographical map of alpine terrain. The tank is filled with water, a dye is injected into the water and a current is run through the water to simulate air flow. Its intended purpose is to demonstrate how a material will disperse in the atmosphere in relation to terrain and air patterns. See 911 F.Supp. at 792 n. 10. However, the water model is just as speculative as the plume movie. In his deposition, Vergeiner testified that the water model was a demonstration and a "tool for visualization," but was not intended "to exactly simulate flows at the time of the TMI accident." App. Vol. V, at 3930-31. In fact, Vergeiner testified that "[t]here's no way to [simulate the complete atmospheric structure] in a simple shallow water model." Id., at 3930. Simply put, the water model does not assist the finder of fact and is, therefore, not admissible under Rule 702.

Most importantly, we note that Vergeiner's proffered testimony about the amount of radioactive materials delivered to the areas where the plume traveled was totally unreliable. That testimony was intended to explain how the hypothesized plume containing the high concentrations of radionuclides (believed to be part of the "blowout") dispersed throughout the Three Mile Island Area exposing the population to high levels of radiation.

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In the field of radiation dose reconstruction,[98] "the amount of radionuclides released from a site over a specific period" is called the "source term". RADIATION DOSE RECONSTRUCTION, at 16. A proper dose reconstruction study should determine the amount of radionuclides released over a specified period as well as the rate of release as a function of time. Id. Consequently, a complete description of the source term "includes what was released and in what form and where and when the release occurred." Id. The National Research Council's Committee on an Assessment of [Center for Disease Control and Prevention] Radiation Studies, has noted that if dose reconstruction studies are credible, they "must rely on solid science, state-of-the-art methods, and careful peer review." Id. at 14. The Committee further noted that "[u]ltimately, a dose reconstruction study will be judged by the scientific community on the basis of the technical quality of the study and its contribution to science." Id.

Vergeiner is a meteorologist and not an expert in radiation dose reconstruction.[99] He admitted that he received the source term he used to calculate the radiation exposure from Trial Plaintiffs' counsel. App. Vol. V, at 4103-04. He

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98. "[D]ose reconstruction is defined as the process of estimating doses to the public from past releases to the environment of radionuclides. . . . These doses form the basis for estimating health risks and for determining whether epidemiologic studies are warranted." RADIATION DOSE RECONSIDERATION, at 7.

99. The District Court specifically found that Vergeiner was not an expert in dose reconstruction or dose estimation. 911 F.Supp. at 797-98. The Trial Plaintiffs do not challenge that finding.

also testified that the gross magnitude of his releases were the same as those postulated by Webb (before Webb recanted his proposed expert testimony)[100] but he admitted that his release times were different than Webb's. Id. However, Vergeiner was not able to explain the difference. Id.

Moreover, Vergeiner violated an elementary principle of credible dose reconstruction in estimating dose exposure. The National Research Council's Committee on an Assessment of CDC Radiation Studies has stated, "[t]he credibility of a comprehensive source term study depends upon confirming that all pertinent documents have been seen and evaluated. Complete records are essential in identifying the source term." RADIATION DOSE RECONSTRUCTION, at 18. However, there is nothing in the record before us that indicates that Vergeiner attempted to verify the source terms he took from Trial Plaintiffs' counsel. Consequently, his dose estimates can not be ruled credible or reliable. Accordingly, they cannot assist a fact finder.

The problem inherent in the source terms that counsel supplied was apparent when Vergeiner's plume concentration hypothesis was tested. In his first report, Vergeiner compared his estimated dose measurement to that recorded by the thermoluminescent dosimeters ("TLD's") in the TMI Radiation Environmental Monitoring Program[101] for the TMI-area community of Middletown, Pennsylvania. Vergeiner accepts that the TLD measured dose from March

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100. See p. 661-62, supra.

101. See p. 659 n. 79, supra.

28, 1979, the date of the accident, to April 28, 1979, was 9.1 mrems (.91 mSv). Vergeiner I, at 10; App. Vol. V, at 3595. But, his estimated dose measurement for Middletown was 200 mrems (2mSv) in only three hours on March 28, 1979. Id. Aside from expressing his basic and fundamental mistrust of TLD's, see, e.g., App. Vol. V, at 4106, Vergeiner was unable to explain the discrepancy between the TLD measured dose at Middletown and his estimate. His best explanation was rather cryptic and enigmatic:

> So the reader has a chance to draw conclusions for himself, even if I may suggest a conclusion, but the reader can check this, these assumptions, and he has a chance to see for himself. He can choose which he believes. He can reduce Webb's estimate, he can do other things.

App. Vol. V, at 3968. However, Vergeiner's testimony must assist the fact finder in understanding the evidence or determining a disputed issue of fact. His cryptic explanation for the difference in dose measurement does neither.

We conclude, therefore, that the District Court did not abuse its discretion in excluding Vergeiner's testimony about issues other than the relevant weather conditions.

ii. Charles Armentrout and Victor Neuwirth.

a. Qualifications.

Charles Armentrout has an undergraduate degree in physics from the University of Maine, a master's degree in

physics from Wesleyan University and a master's degree in radiological physics from Columbia University College of Physicians and Surgeons. He is an Associate Professor at the University of Southern Maine. Victor Neuwirth has an undergraduate degree in chemistry from the State University of New York at Stony Brook and a master's degree in Chemistry from the State University of New York at New Paltz. He is a laboratory associate and Professor of Chemistry at the University of Southern Maine. Armentrout and Neuwirth authored a joint report for the Trial Plaintiffs (Affidavit of C.E. Armentrout and Victor J. Neuwirth, App. Vol. VIII, at 7339-65);[102] however, the District Court discussed their proffered testimony separately.

Armentrout's proffered testimony based on his own observations and experiences covered two separate areas: (1) a discussion of what he called "anomalously high" radiation readings registered shortly after the TMI-2 accident; and (2) a discussion of radiation survey meter readings allegedly recorded by a local resident during the TMI-2 accident.[103] Neuwirth's proffered testimony concerned the

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102. Armentrout and Neuwirth prepared an original report and a revision. The original report is dated February 20, 1995, and the revision is dated May 11, 1995. The revision makes no substantive changes to the original report, it merely corrected some mathematical errors. App. Vol. VIII, at 7827.

103. Armentrout's proposed testimony also covered two other areas. He was to testify about the results of analyses of soil samples taken from Three Mile Island and surrounding areas that Neuwirth performed at his request. He was also to give an explanation of the rate-dependent behavior of Geiger-Muller radiation detectors. (Cont'd)

results of his analyses of soil samples taken from Three Mile Island and the surrounding area. He performed his analysis at Armentrout's request. Then, based on Neuwirth's analyses, Armentrout made radiation dose exposure estimates.

b. Armentrout's Observations and Experiences.

In his written report, Armentrout wrote that on March 31, 1979, he and a former student assembled radiation detection equipment on the roof of the science building at the University of Southern Maine. The equipment consisted of a gamma-beta Geiger-Muller detector, pre-amplifier and count divider. Affidavit of C.E. Armentrout and Victor Neuwirth, at 2-3; App. Vol. VIII, at 7340-41. In his report he wrote, and at the in limine hearing he testified, that the detection equipment recorded two "anomalous bursts" of radiation activity. Affidavit, at 3; App. Vol. VIII, at 7341; Tr. at 1249; App. Vol. VIII, at 7769. He described the bursts as "significant radioactive sample[s] . . . detectable and identifiable only then as being mixed beta-gamma radiation." Affidavit, at 3; App. Vol. VIII, at 7341. He memorialized

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However, in an unpublished order and opinion, the District Court precluded Armentrout from testifying as to the substance of Neuwirth's soil sampling analyses. In re TMI, No. 1:CV-88-1452, 1995 WL 848519 (M.D.Pa. Nov. 9, 1995). The Trial Plaintiffs do not challenge that ruling. Armentrout's proposed testimony about Geiger-Muller radiation detectors was not discussed by either party in the District Court. 911 F.Supp. at 799 n. 22, and the Trial Plaintiffs do not discuss it in the brief they filed in this appeal. Consequently, we assume that this portion of Armentrout's proposed testimony has been abandoned by the Trial Plaintiffs. In any event, the issue is clearly waived.

his observations in a letter to the President of the University of Southern Maine. Exhibit A to Affidavit; App. Vol. VIII, at 7367-72. In addition to his own observation of anomalous bursts of radiation, Armentrout's report claims that "one or more governmental installations near Portland," Maine, recorded radiation readings similar to those he recorded. Affidavit, at 4; App. Vol. VIII, at 7342. Armentrout also notes that an article in the February 8, 1980 issue of SCIENCE magazine reported that elevated levels of Xenon-133 (133Xe) were recorded in Albany, New York, on March 29 and 30, 1979. In the opinion of the authors of that article, the increased levels of 133Xe "could be attributed to releases from the Three Mile Island reactor accident." App. Vol. VIII, at 7375. Armentrout believes that the SCIENCE magazine article confirms his conclusion based on his recorded bursts of radiation activity, that the TMI plume passed over the area. Affidavit, at 4; App. Vol. VIII, at 7342. However, Armentrout candidly admitted that his observed readings did not tell him what radionuclides were released as a result of the accident or how large the releases were. Tr. at 1290; App. Vol. VIII, at 7810.

The defendants did not challenge Armentrout's qualifications as an expert. Rather, they argued that this portion of his proffered testimony would not be helpful to the trier of fact. The court declined to "trudge through the Daubert/Paoli II" analysis and simply found that this portion of Armentrout's proffered testimony does not " 'fit' within any material fact in issue." 911 F.Supp. at 800. Consequently, the court precluded Armentrout from testifying about his observation of anomalous bursts of radiation. Id.

Armentrout was also proffered to testify about efforts he made to verify radiation readings taken by residents living near Three Mile Island during the accident. In his report, he wrote that in 1992 he had several telephone conversations with a man who lived on the west shore of the Susquechanna River opposite Three Mile Island in Etters, Pennsylvania. According to Armentrout, that man claimed that he was trained in the use of radiation detection instruments and said that he had recorded and preserved "significant gamma emissions from TMI made in the time-frame of the accident." Affidavit, at 24; App. Vol. VIII, at 7362. Armentrout located similar instruments and traveled to the Three Mile Island area to visit the man and verify the readings. However, Armentrout could not find him. Nonetheless, Armentrout met a neighbor of the man who remembered that he (the neighbor) and the man Armentrout was seeking had purchased identical detection instruments. The neighbor told Armentrout that he took a reading during the accident that sent his detection instrument off scale. Armentrout opined that this conversation verified the missing man's reports of high readings taken during the accident.

Not unexpectedly, the defendants challenged this portion of Armentrout's proffered testimony as being totally unreliable, rank hearsay. The District Court agreed and precluded this portion of Armentrout's proffered testimony. 911 F.Supp. at 800-801.

c. Discussion and Conclusion.

We conclude that the District Court properly precluded both portions of Armentrout's proffered testimony. His

testimony about his attempts to verify the high radiation readings made by the unidentified man in Etters is purely anecdotal and any reliance on the unconfirmed Etters readings is totally lacking in scientific reliability. Moreover, his proffered testimony about the readings of bursts of radiation activity fails to satisfy the helpfulness prong of Rule 702. Armentrout's equipment on the roof of the university's science building recorded two bursts of radiation activity. Those two observations, his claim that government installations around Portland, Maine, recorded similar activity, and the article in SCIENCE magazine, form the basis of his conclusion that the TMI plume passed over the northeastern part of the United States.

Rule 702's "helpfulness" or "fit" prong "requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility." Daubert, at 592, 113 S.Ct. 2786. Armentrout merely assumed that his observations of two bursts of radiation activity were the result of the TMI plume passing over his area of southern Maine. That assumption is supported by nothing other than conjecture, and we do not believe that the District Court erred in ruling the evidence inadmissible under Rule 702.

Moreover, assuming arguendo that Armentrout's opinion that the TMI plume passed over the northeast United States has scientific reliability, his opinion still would not be helpful to the trier of fact. The Trial Plaintiffs proffered Armentrout's testimony in an effort to demonstrate that they were exposed to levels of radiation sufficient to cause their injuries. They based their trial strategy on the theory that as a result of the accident, they were exposed to an equivalent dose of at least

10 rems or 100 mSv each.[104] However, Armentrout admitted that he could not tell with any degree of scientific certainty how large the radioactive releases from the accident were. The connection between his testimony and a crucial fact in issue, i.e., whether the Trial Plaintiffs were exposed to equivalent doses of 10 rems or 100 mSv each was tenuous at best because he could not testify as to the magnitude of the releases of radionuclides.

d. Neuwirth's Soil Sample Analyses and Armentrout's Dose Estimates.

As noted above, Neuwirth performed analyses of soil samples obtained from the Three Mile Island area at Armentrout's request. Neuwirth concentrated the soil samples by chemical extraction and used a sodium iodine detector to take integrated counts of radionuclides. Affidavit, at 7-9; App. Vol. VIII, at 7345-7347. Although Neuwirth found that certain Three Mile Island area soil samples contained radioactive materials, he was unable to identify specific radionuclides. Affidavit, at 21; App. Vol. VIII, at 7359. Because he was unable to identify any specific radionuclide, Armentrout directed him to calculate the half-life of each sample as a whole. Neuwirth calculated the gross activity of the samples in 1994 and then recounted the gross activity of the same samples one year later in 1995. Based on these two points, Neuwirth calculated a generalized half-life calculation for each of the samples. Affidavit, at 14-15; App. Vol. VIII, at 7352-53. From the analyses of the soil samples and the calculation of the gross activity of the

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104. See p. 659, supra.

samples, Neuwirth and Armentrout concluded that the gross radioactivity in the Three Mile Island soil samples was attributable to fission products from the reactor accident. Affidavit, at 20; App. Vol. VIII, at 7358 ("Thus, these decay data and at least some of the test results lead us to infer that significant quantities of nongaseous primarily beta-emitting fission product nuclides were released in the TMI event.").

Armentrout then used the half-life calculations to make dose estimates. He attributed the difference between the two counts to the decay of fission products having a half-life of about one-year,[105] such as cesium-134 (134Ce) or cerium-144 (144Cr). Affidavit, at 16, 23; App. Vol. VIII, at 7354, 7361; see also Affidavit, at 21; App. Vol. VIII, at 7359 Extrapolating back to 1979, the year of the accident, Armentrout opined that there must have been thousands of times the amount of fission products in the soil then. Affidavit, at 16; App. Vol. VIII, at 7354. For example, the gross activity of soil sample no. 19887 was measured to have 1.2 picocuries per gram in 1995, Affidavit, at 15; App. Vol. VIII, at 7353, which Armentrout extrapolated back to a 1979 activity of 320,000 picocuries per gram.[106] Affidavit, at 16; App. Vol. VIII, at 7354.

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105. Armentrout attributed the difference in gross activity between the two counts to radionuclides having a half-life of about one year because radionuclides having extremely short half-lives would have disappeared from the samples and no activity would be detected in the year interval between 1994 and 1995, while radionuclides having long half-lives are regarded as stable and no activity would be detectable in just one year. App. Vol. VIII, at 7822. Further, Armentrout regarded radionuclides having half-lives of about one year to be not naturally occurring and, therefore, fission products. Id. at 7794.

106. A pico is one-trillionth (10-12) of a given unit. MEDICAL EFFECTS, APPENDIX III, CONVERSION TABLES.

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Although Neuwirth's expert qualifications were accepted, his proffered testimony was challenged as lacking "fit." Defendants argued that no valid connection could be made between the results of his soil samples and the TMI accident. Armentrout's extrapolation back was also challenged as lacking scientific reliability. After a Daubert/ Paoli II analysis, the District Court found that neither opinion was derived from scientific method and neither represented good science. Therefore, the court precluded Neuwirth and Armentrout from testifying. 911 F.Supp. at 804.

e. Discussion and Conclusion.

We find no error in the Court's ruling. Neuwirth and Armentrout hypothesized that the radioactive decay that Neuwirth's analyses found in the TMI soil samples was directly attributable to fission products released to the environment by the reactor accident. That hypothesis is testable, and it was in fact tested. However, the results of that testing undermined Neuwirth's conclusions.

Because Neuwirth was unable to discover any specific radionuclides causing the activity he found in his analyses, Armentrout sent portions of the samples to Data Chem laboratory. That lab was to perform a spectrographic analysis capable of identifying specific radionuclides and activity levels for each identified radionuclide. App. Vol. VIII, at 7812-13. Data Chem's analyses found that the overwhelming portion of the activity in the samples was the result of naturally occurring background radionuclides. App. Vol. VIII, at 7887-89; see also App. Vol. VIII, at 7636 and App. Vol. XIV, at 11679-87. The only fission product found by

Data Chem was cesium-137 (137Ce). Armentrout testified in his deposition that 137Ce was "ubiquitous" because of fallout from nuclear weapons testing[107] and because it is a fallout product from the Chernobyl accident. App. Vol. VIII, at 7468. Consequently, Armentrout conceded that it was impossible to determine the source of 137Ce. Id.

However, Armentrout did not modify his hypothesis as a result of the Data Chem findings:

> Q: Did you factor into your revised report any of the information communicated to you in the Data Chem report?
>
> A: No, I never have.

App. Vol. VIII, at 7819. Daubert recognized that science is "an empirical endeavor in which testing plays a crucial role." REFERENCE MANUAL ON SCIENTIFIC EVIDENCE, at 71. Indeed, a "key question to be answered in determining whether a theory . . . is scientific knowledge that will assist the trier of fact [is] whether it can (and has been) tested." Daubert, at 593, 113 S.Ct. 2786.

Here, the hypothesis was undermined by Data Chem's testing, yet the hypothesis was not further modified or explained in view of Data Chem's "analysis." Armentrout and Neuwirth's failure to properly revise their attribution of the gross radioactivity in the soil samples to fission products from the reactor accident is the antithesis of good science and dramatically undermines their proffered opinions.

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107. See p. 647, supra.

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Moreover, the half-life back calculation methodology Armentrout used to estimate the levels of fission products released during the accident was based on an assumption that the gross activity in the samples was due to fission products. Armentrout's own testimony established the flaws in that approach. Since he was unable to identify any specific radionuclides in the soil samples, Neuwirth calculated the gross activity in the samples at two points in time and determined the decay rate in the samples. Then, Armentrout made an assumption that the gross activity in the samples was due to fission products released in the accident and that the decay rate Neuwirth calculated established the half-life of the fission product radionuclides. He then extrapolated the levels found in 1994 back to 1979 and concluded that the samples had been contaminated with high levels of fission product nuclides as a result of the reactor accident. However, the flaw in Armentrout's half-life calculation methodology lies in the fact that, as Armentrout's report conceded, "all soil samples contain some natural radioactive materials." Affidavit, at 16; App. Vol. VIII, at 7354. Consequently, it is impossible to determine the half-life of any particular radionuclide in a sample which has an admittedly unknown mix of radionuclides, because any observed decline in activity may be due to a mix of radionuclides with short half-lives and radionuclides with long half-lives. Armentrout admitted as much in his deposition:

> Q: Are you actually counting the half-life of any particular radionuclide or are you actually counting the decrease in counts of the mixture?

A: What we're doing is taking the two, a pair of values for any of the sources, any of the numbers, sample numbers.

Q: And these are all integrated counts, aren't they?

A: Those are all integral counts, yes, and we're taking the value of the later time and the earlier time and a known time in between and calculating from, for the exponential decay law what the effective half-life of that material is, based upon these data.

Q: The effective half-life of the material is not referring to any particular radionuclide, but a mix of whatever is in there, correct?

A: That's very true.

Q: So it may be a large decay of something with a short half-life or a small decay of something with a very long-half life, correct?

A: That's correct.

Q: Is it appropriate, given that range, to arrive at any conclusion concerning the half-life of any particular radionuclide?

A: Depending upon what's in the mix, it could or couldn't be.

> Q: And you don't know what's in the mix, correct?
>
> A: Well, if we examine each of the spectra we could see, for example, there is or is not any cesium which is 30 years. Over a year's span of time the long half-life material like cesium would be level. In other words, wouldn't raise or lower the base. Anything else in there that I can think of, the natural stuff like the uranium decays would be all along. Anything that's short, weeks or months or whatever, would have been gone, so they would be zero. So if you don't have many items in there, then I think your data are all right, at least temporarily.
>
> Q: On a tentative basis?
>
> A: Tentative basis, yes, for a one-year span for two readings. Nobody is saying it's probative, but we want to keep watching these to see how the decay, because then you can plot the picture of the curve and begin to get its shape. . . .

App. Vol. VIII, at 7503 (emphasis added). Trial Plaintiffs now complain because the District Court refused to admit testimony of a witness who conceded that his opinion was not probative of the very issue the Trial Plaintiffs sought to establish through that testimony. Moreover, Armentrout conceded that using only two points in time, one year apart, to count the activity in the samples, does not tell anything about the sample other than the average half-life for the entire mix of radionuclides. He testified that:

> If you have a mixture of materials and you do this kind of work, you are going to get I suppose an average half-life for the mix. But I am not sure what it means.

App. Vol. VIII, at 7793.

Armentrout's assumption that the gross activity in the soil samples was due to fission products was not supported by his own methodology. He essentially admitted that the methodology of counting gross activity in the samples at only two points in time to establish a half-life of the radionuclides in the sample would not enable him to identify any specific radionuclide, let alone a fission product radionuclide, but would only produce an average half-life for the entire mix of unknown radionuclides. His assumption that the activity was due to fission products remains just that, an assumption. Although Daubert/Paoli analysis does not preclude testimony merely because it may be based upon an assumption, the supporting assumption must be sufficiently grounded in sound methodology, and reasoning to allow the conclusion it supports to clear the reliability hurdle. Assumption-based conclusions that do not meet that test can hardly be relied upon as "good science." Here, Neuwirth made an intermediate count of one of the soil samples and discovered that 75% of the activity disappeared in one month. This, in turn, suggested that the radionuclide in the sample was not a fission product radionuclide but rather naturally occurring radon. App. Vol. VIII, at 7495-96.

Consequently, because Armentrout's attribution of the difference between the two counts to the decay of fission

products was an assumption based on a flawed methodology, Armentrout's use of data derived from that assumption to extrapolate back to 1979 to arrive at the conclusion that the soil samples were contaminated with high levels of accident released radionuclides was completely lacking in scientific validity and reliability. Because the methodology used to produce the data upon which Armentrout extrapolated back to arrive at dose estimates lacked scientific validity and reliability, we need not determine whether "extrapolation back in time, using known levels of compounds and a scientifically valid mathematical formula for the extrapolation, would meet the standards of Rule 702 and Daubert." Heller v. Shaw, 167 F.3d at 162. The data which Armentrout developed from his flawed methodology was unreliable and it came to be morphed into "good science" by scientifically valid mathematical back-extrapolation.

Accordingly, the District Court did not abuse its discretion in excluding Neuwirth and Armentrout's soil sample analyses, the half-life calculations and extrapolated dose estimates.

iii. James Gunckel

a. Qualifications.

James Gunckel is a biologist who earned an undergraduate degree from Miami University (Ohio) and a master's degree and Ph.D. from Harvard University. He is a Distinguished Professor emeritus at Rutgers University in New Brunswick, New Jersey. Before his retirement he was, at various times, Chairman of the Botany Department,

Chairman of the Radiation Science Center, Chairman of the Department of Radiation and Environmental Health and Safety, and Chairman and Organizer of the Health Safety Council. In addition to his academic and administrative appointments at Rutgers, Gunckel collaborated, over a twenty year period, with the late Arnold A. Sparrow, Ph.D., at the Brookhaven National Laboratory, studying the effects of radiation on plants. He is, as the District Court acknowledged, "a pioneer in the area of studying radiation effects on plants." 911 F.Supp. at 809. His report consisted of an evaluation of trees in the Three Mile Island area which he opined were damaged by radiation and an investigation he made of TMI area residents who claimed to have experienced radiation induced symptoms. His involvement as an expert witness began in 1987, eight years after the reactor accident. Based on his evaluation and investigation, Gunckel opined as to the radiation dose to which the trees and the residents were exposed.

b. Gunckel's Opinion.

Gunckel believed that prior estimates of the amount of radiation released as a result of the accident were unreliable. Gunckel Affidavit of May 13, 1993, at 1-5 (hereinafter "1993 Affidavit"). Thus, he devised a method of estimating dose exposure based on his work with Dr. Sparrow at the Brookhaven National Laboratory where they created a gamma field to irradiate plants in order to study the effects of the radiation on the plants. The gamma field was operated as follows:

> [t]here was a cobalt-60 source, for gamma radiation, in the center of the field. The plants,

> mostly seedlings and cuttings, were planted in concentric rows around the source and planted so that successive rows reflected a "doubling dose" concept, for one could expect that to double the dose could double the effect. The source was lowered below the ground to permit entry for two hours of watering, cultivation and data taking. The observations centered on slight and severe growth inhibition or a lethal dose to growth processes from both chronic and acute exposure.

1993 Affidavit, at 5-6; App. Vol. V, at 3320-21. Gunckel testified at the in limine hearing that, except for the two hours a day that the gamma source was lowered into the ground, the plants were constantly irradiated through the growing season, i.e., April through November, for a period of 20 years. App. Vol. V, at 3485. The plants, randomly designated, but consisting of hardwoods as well as conifers, were exposed to a controlled amount of radiation, ranging from an absorbed dose of 2,000 rads (20 Gy) for the plants closest to the gamma source to 2 rads (20 mGy) for the plants farthest from the gamma source. Id. at 3484.

Gunckel explained that irradiation has direct and indirect effects on plants. The two most import direct effects are mitotic delay and cell death, both of which are due to damage to the nucleus of the plant. 1993 Affidavit, at 7; App. Vol. V, at 3322. The most significant indirect effect is growth inhibition. 1993 Affidavit, at 6; App. Vol. V, at 3321.

From their observations of the effects of the irradiation on the plants in the gamma field, Gunckel and Sparrow

determined the dose needed to cause a certain effect in a plant. App. Vol. V, at 3484 ("That was our basic objective, and the basic objective was simply to create a data bank of correlating dose with effects on a variety of plants."). Applying his work at Brookhaven to the TMI reactor accident, Gunckel hypothesized that:

> Radiation induced growth effects in trees would occur in areas where residents experienced symptoms indicating exposures to radioactivity at the time of the TMI accident and that those tree effects would occur in several species showing relative sensitivities (slight and severe growth effects, and lethality) corresponding to those determined in Brookhaven.

Gunckel Affidavit of October 23, 1995, at 12 (hereinafter "1995 Affidavit"); App. Vol. V, at 12. Using the Brookhaven gamma field data, Gunckel found three species of trees which are present in the Three Mile Island area for which there was radio sensitive data from the Brookhaven experiments. 1993 Affidavit, at 9; App. Vol. V, at 3324. Those trees were spruce, pine and Norway maple. Id.

Pursuing his hypothesis, Gunckel interviewed 15 residents of the TMI area regarding the health effects they experienced as a result of the reactor accident.[108] App. Vol.

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108. Gunckel described the radiation induced health effects as "malaise, metallic taste, cessation of menses, epilation, sore throat, petechiae, diarrhea, conjunctivitis and rhinitis," which indicate the radiation sickness syndrome of 100-300 rems [1-3 Sv]. 1993 Affidavit, at 11; App. Vol. V, at 3326.

V, at 3490-92. He interviewed the residents not to determine whether "what they complained of was true or false." Id. at 3490. Rather, he was "trying to associate people with possible episodic evidence [of radiation induced symptoms] with a plant indicator." Id. Based on his interviews, Gunckel concluded that 5 of the 15 people were exposed to erythemic doses, i.e., an equivalent dose sufficient to cause erythema.[109] Id. at 3492. He testified that an erythemic dose is between 300 rems (3 Sv) and 360 rems (3.6 Sv). Id. at 3496. Consequently, he concluded that an equivalent dose of 300-360 rems was "the top dose at TMI that we could recognize by our yardsticks." Id.

After identifying the areas where residents described health effects purportedly related to the reactor accident, Gunckel searched for damaged trees in those areas. As a result of his search, he observed "lethal effects . . . in more than 80 spruce, pine and maple trees up to 15 miles from the TMI facility." 1993 Affidavit, at 10; App. Vol. V, at 3325. He reported:

> Slight to severe growth inhibition and lethal (or sublethal) damage was observed in all three species. In the spruce, lethal effects were more easily identified since, when the terminal bud is killed, there are no axillary buds to replace it, so the top of the spruce appears as a dead skeleton of branches. In the pine, when the terminal bud is killed, the six to eight axillary buds develop into major branches, giving the tree an apparently flat

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109. See p. 639 n. 40 and p. 641-42, supra.

top. This effect is comparable to the effect found in the pine trees at Chernobyl.

Sub-lethal radiation speeds up maturation so that in the maples, the leaves abscise. They form a corky layer at the leaf base, cutting off the water supply, causing the leaves to fall. The inner bark contains conducting tubes (phloem) which transport sugars. The phloem tissue is made up of enucleate sieve cells with adjacent companion cells. These companion cells with very large nuclei are targeted by the radiation, die and lesions form in the bark. Death results over a period of time when the sugar supply to the older part of the tree is exhausted. The acute lethal dose to spruce . . . is 1,020 rem [10.02 Sv]. The acute lethal dose to the apical meristems of white pine branches . . . is 1,000 rem [10 Sv]. The sub-acute lethal dose for maples . . . is 3,000 rem [30 Sv]. The maple received the same 1000 rem dose as the spruce or pine. . . . To have observed the lethal and sublethal effects near TMI, doses of this magnitude had to have occurred. The dose which killed the chromosomes in the spruce by a direct effect on the target . . . is the same dose as is responsible for the indirect effect which caused the range of slight to severe growth inhibition, a morphological lethal dose, which is the indirect effect.

1993 Affidavit, at 9-10; App. Vol. V, at 3324-25. He then explained that "[t]he doses which caused injury to the nucleus

of cells in plants will also injure the nucleus of cells in animals and humans." 1993 Affidavit, at 12; App. Vol. V, at 3327. Accordingly, he concluded that because the damage to the trees was caused by exposure to very high levels of radiation, the health effects suffered by the TMI residents he interviewed "cannot be dismissed as unrelated to the TMI accident on the a priori belief that doses were too low." Id. Consequently, as a result of his investigation, Gunckel offered his opinion that "during the early days of the TMI accident, individuals received erythemic doses in the range of 300 to 1000 rems [3 Sv to 10 Sv]." 1993 Affidavit, at 12; App. Vol. V, at 3327.

The District Court excluded all of Gunckel's proffered testimony. It found that Gunckel's methodologies of investigation of human health and as to his tree studies "lack scientific validity and reliability pursuant to Rule 702." 911 F.Supp. at 810. It also found that because Gunckel is not a medical doctor he is not qualified "to opine as a medical expert with respect to his human . . . health study." Id. The court also held that Gunckel's testimony lacked "fit" because he was unable to verify that the tree damage occurred at the time of the TMI accident, rather than at some earlier or later date. Id. Finally, the court found that Gunckel's dose estimates are logically inconsistent "with the lack of human casualties in the areas where the tree damage was noted." Id.

c. Discussion and Conclusions.

At the outset, the Trial Plaintiffs contend that the District Court misunderstood the purpose of Gunckel's interviews of TMI area residents who claimed to have suffered radiation

induced medical symptoms. They submit that Gunckel sought medical information from those people, not to render diagnoses, but rather to help him identify geographical areas surrounding TMI where he could pursue his hypothesis and begin to search for radiation-damaged trees. Trial Plaintiffs' Br. at 21 n. 31. They assert that the court's Daubert/ Paoli II admissibility analysis was flawed from the start because of a fundamental misunderstanding of Gunckel's study. We disagree.

While Gunckel's stated purpose in interviewing the residents about their allegedly radiation-induced medical conditions may have been as the Trial Plaintiffs claim, it is clear that he strayed far afield from that stated purpose and diagnosed 5 residents as having radiation-induced erythema. App. Vol. V, at 3535-36; see also 1993 Affidavit, at 11; App. Vol. V, at 3309 ("The fact that erythemic responses also occurred in many cases at TMI clearly established that there was a higher level of exposure. A resident, in the WNW sector living about 10 miles west of TMI at 900 feet elevation . . . experienced a classical case of erythema from only a few minutes exposure on March 30, 1979."). Although Gunckel is a respected scientist, he is neither a medical doctor nor a health physicist.[110] So far as the record is concerned, his only knowledge of the health effects of radiation was obtained from literature he reviewed in connection with his retention as an expert in this litigation. App. Vol. V, at 3388. He plainly does not meet Rule 702's "Qualifications" requirement and cannot, therefore, offer an expert opinion

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110. "Health physics is the name given to the study of problems related to the protection of man from exposure to radiation." LAMARSH, at 397.

as to radiation-induced medical conditions. See Paoli II, at 741.

Gunckel's opinion as to the radiation damaged trees is less problematic, especially considering his acknowledged expertise in the area of radiation effects on plants. Essentially, Gunckel found trees which he claimed were damaged by radiation, and, using the results of his work at Brookhaven, he extrapolated back to determine the dose which caused the damage. At the in limine hearing, he explained his methodology as follows:

> Q: We need to establish the relationship of your technique to methods which have been established to be reliable. Now, your technique, let's talk about your technique at TMI. Does that relate to reliable standards and methods which you used at Brookhaven? Is there a relationship between the two?
>
> A: Oh, there's a relationship. But we can't take much credit for what we did at TMI. All we did was observe the results. And you go backward. We did the original going from dose to results. All we did was observe the results at TMI and go to Brookhaven for the dose.
>
> Q: And you used, as I understand it, the information and data that you accumulated at Brookhaven to reach the conclusions you reached here, correct?

A: Correct.

Q: And I think you've already indicated that the Brookhaven data is very reliable, correct?

A: Correct.

App. Vol. V, at 3516-17.

However, the District Court was critical of Gunckel's methodology. The court stated that the "TMI tree studies bear no functional relevance to the Brookhaven studies." 911 F.Supp. at 807. The court believed that the Gunckel's TMI tree study bore little methodological relationship to the Brookhaven studies because the Brookhaven studies involved cellular and subcellular evaluations to determine the extent of radiation damage while Gunckel's TMI tree study involved simply observing morphological damage to trees. Id. at 807 n. 36. However, we believe that the District Court's criticism of Gunckel's TMI tree study methodology was inappropriate. Although the focus of the Brookhaven radiation studies was cellular and subcellular, see App. Vol. V., at 3485 ("our ultimate objective was to predict doses based upon chromosome volume, or nuclear volume."), Gunckel testified that his work at Brookhaven also involved observing morphological damage to trees:

Q: [D]id you have the opportunity to visibly observe the trees and the effects that the irradiation was having on them?

A: Yeah, absolutely. This was done on a daily basis. . . .

* * *

> Q: As a result of that experience for those 20 years that you've just discussed, are (sic) you able to visibly observe the radiation effects on conifers?
>
> A: Yes. Within the limits of those that we studied, yes. We didn't study them all.

App. Vol. V, at 3485-86. Consequently, so long as Gunckel could demonstrate that his work at Brookhaven involved mature trees, and not tree seedlings, and that he performed differential diagnoses on the trees he studied at TMI to rule out other causes for the damage he observed (both of which he did)[111] Gunckel's TMI tree study methodology is not as flawed as the District Court believed.

Gunckel's methodology lies in its novelty. It has, apparently, only been used in this litigation. Gunckel candidly admitted that during his years at Brookhaven he never worked in reverse to determine dose from observed damage. He testified:

> Q: I appreciate that you have spent your professional career studying the effects of a known amount of radiation on the development

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111. There was a factual dispute in the District Court as to whether the Brookhaven study involved mature trees, as opposed to seedlings, and whether Gunckel performed differential diagnoses on the trees he claimed were damaged by radiation to rule out other causes for the damage, most notably insects and certain fungi. However, the district court resolved that factual dispute in Gunckel's favor. 911 F.Supp. at 808; 809.

> of trees. Have you ever, in your professional career, tried to do the reverse and test it? In other words, try to infer a dose from what you see in a tree and then test it to see if your inferred dose was reasonably accurate?
>
> A: No. We didn't get that far. It took us 20 years to get this other data together. This is not an easy thing to do. We simply hadn't gotten that far. And then Arnold Sparrow up and died in the midst of all this, so that ended the whole project.

App. Vol. V, at 3392. However, the quality of a given study does not necessarily correlate to the novelty of its methodology. Gunckel's TMI tree study is rooted in the kind of methodology that gives his study validity and reliability, notwithstanding the novelty of what he did, or the fact that his study was undertaken for this litigation. If the Brookhaven studies demonstrate that irradiation in the amount of dose a will result in z amount of radiation damage to a tree, we believe that a scientist of Dr. Gunckel's renown (20 years of his professional life studying the effects of known amounts of irradiation on trees at Brookhaven) can certainly observe damaged trees and determine the dose of radiation necessary to cause the observed damage, so long as adequate and competent differential diagnoses are performed.

Defendants argue that Gunckel's methodology is unreliable because it is impossible to determine dose from observed damage. In support of that argument, they cite Gunckel's collaborator at Brookhaven, Dr. Sparrow, who was of the opinion that while "stunted or dwarfed plants,

misshapen organs, or mottled flowers or leaves are often the results of radiation .... external examination of such abnormal plants will provide very little information as to the basic cause of these effects." Arnold H. Sparrow, Brookhaven Lecture Series, The Role of the Cell Nucleus in Determining Radiosensitivity, May, 16, 1962, at 1. However, this apparent dispute between the two collaborators does not render Gunckel's methodology unreliable. The dispute goes to the weight to be afforded Gunckel's expert opinion, not the reliability of his methodology. In a Daubert/Paoli II analysis, the focus is not on determining "which of several competing scientific theories has the best provenance." Ruiz-Troche v. Pepsi Cola of Puerto Rico Bottling Co., 161 F.3d 77, 85 (1st Cir.1998). Rather, we focus on determining whether the "opinion is based on valid reasoning and reliable methodology." Kannankeril, 128 F.3d at 806.

No one can seriously suggest that Gunckel's work at Brookhaven was not good science. We believe that the methodology Gunckel used in his TMI tree study meets the Daubert/Paoli II admissibility requirements in so far as methodology is concerned. See Paoli II, at 745 n. 14 (suggesting that if expert uses a methodology only slightly different from a clearly reliable methodology, the court should be more likely to accept the altered methodology than if it was evaluating the altered methodology as an original matter).

That is not to say, however, that the District Court abused its discretion in excluding Gunckel's proffered testimony. Although Daubert insisted that the focus of the admissibility inquiry "must be solely on principles and methodology, not

on the conclusions that they generate," Daubert, at 595, 113 S.Ct. 2786, the Court subsequently amplified that principle in Joiner. There, the Court wrote:

> conclusions and methodology are not entirely distinct from one another. Trained experts commonly extrapolate from existing data. But nothing in either Daubert or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the ipse dixit of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.

118 S.Ct. at 519. Consequently, although principles and methodology remain the focus of a Daubert inquiry, "this focus need not completely pretermit judicial consideration of an expert's conclusions." Ruiz-Troche v. Pepsi Cola of Puerto Rico Bottling Co., 161 F.3d at 81; see also Heller, at 153, 161 (holding that district court was correct when it questioned an expert's conclusions).

When Gunckel's ultimate conclusions are examined, it is clear that they must be rejected, not simply because they could not "reliably flow from the facts known to the expert and the methodology used," Heller, at 153, but rather because they fly in the face of reality. Gunckel's written opinion concludes that during the early days of the reactor accident, "individuals received erythemic doses in the range of 300 to 1000 rems, depending upon the isotopes to which they were exposed." 1993 Affidavit, at 12. At the in limine hearing,

Gunckel testified that although a dose of 1,000 rems was the dose to the trees in the TMI area, a dose of 300-360 rems was a "credible" dose range for humans. App. Vol. V, at 3501. But, he admitted that a dose of 360 rems is the "official lethal dose" for humans. Id. at 3498. He testified: "That's an LD50/60. In other words, 50 percent of the population would die from that dose in 60 days." Id.

Thus, equivalent doses between 300 to 1000 rems are extremely high. They are so high that such doses would have caused deterministic effects in the population living around Three Mile Island.[112] Yet, except for Gunckel's claim that he discovered 5 people who suffered from radiation-induced erythema, the record does not demonstrate, and the Trial Plaintiffs do not contend, that anyone living in the area surrounding Three Mile Island ever reported a deterministic effect caused by the fission product radionuclides released from the TMI accident to any health care provider or health care facility.[113] Similarly, even though Gunckel admitted that

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112. See p. 641-42, supra.

113. The record does contain a study commissioned by the defendants which concluded that from June 30, 1978 to June 30, 1993, there were no increases in hospital utilization that can be attributed to the reactor accident. See Larry R. Fosselman, A Look at Hospital Utilization Relative to Three Mile Island 3 (July 14, 1995) (unpublished) (App. Vol. XII, 10234-38). Fosselman's report recites that he was asked "whether any data exists which might tend to prove or disprove the hypothesis that the TMI accident in March, 1979, produced any changes in health evidenced by demand on the services of acute health care providers." Id. at 1. His conclusion, based on a review of hospital utilization data and his personal

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a dose of 360 rems is a lethal dose, the record does not reflect an epidemic of human casualties near the allegedly found radiation damaged trees.[114] In fact, if these disputed dose estimates are correct, we would expect that half of the population around Three Mile Island would have died within 60 days of the nuclear accident there. Obviously, that did not happen.

Consequently, given the complete lack of any reports of deterministic effects following the reactor accident, and the undeniable reality that statistically significant human casualties did not occur following the accident, Gunckel's conclusions are not trustworthy. Thus, the District Court did not abuse its discretion in excluding Gunckel's testimony in its entirety.

(Cont'd)
observations, is "that the March 28, 1979, Three Mile Island accident caused no detectable adverse health effects in the relevant seven-county area as demonstrated by hospital utilization and health care provider reports." Id. at 5.

114. Gunckel attempted to explain that while the lethal dose for humans is 360 rems, the "lethal" dose is not really lethal. He testified: "The official lethal dose for humans is 360. . . . But that isn't people. That's the other thing you have to watch. That's laboratory animals. And you can't do experiments on people and get data like that. So that's the reason why you can't dwell on these so-called lethal doses or even think for a moment that they are lethal. They aren't." App. Vol. V, at 3498. However, even assuming arguendo that the reported lethal dose of 360 rems is imprecise, the absence of any reported deterministic effects would still undermine Gunckel's conclusion to the extent that we doubt it could survive a Daubert inquiry even then. 360 rems is undeniably an extremely high dose even assuming that it is not lethal.

Appendix A

iv. Vladimir Shevchenko.

a. Qualifications.

Shevchenko is a scientist from the former Soviet Union who has a Ph.D. in Biological Sciences. His area of expertise is radiation genetics, with particular emphasis on the cellular and subcellular effects of radiation on plants. App. Vol. VI, at 4519. He also has experience in cytogenetic studies on chromosomal aberrations in human lymphocytes. Id. at 4199. From 1962 to the present, he has studied the effects of ionizing radiation on plants and animals in the Eastern Ural Radiation Belt, the site of a nuclear accident which occurred in 1957 at the Mayak military plant where atomic weaponry was produced. Id. In addition, he has studied radiation effects on plants and animals in the Chernobyl region since shortly after the nuclear accident there in 1986. Id. Since 1993, he has participated in a study of the people and the environment at the Semipalatinsk Nuclear Testing Grounds where people were exposed to ionizing radiation as a result of nuclear weapons testing. Id. He has been Scientific Advisor to the Russian Parliament on the effects of the Chernobyl accident, Chairman of the Radiation Genetics Section of the Scientific Council on Radiobiology of the Russian Academy of Sciences, and Advisor on Radiation Genetics to the United Nations. Appellants' Br. at 27. Shevchenko received the Red Banner Award for his work on the Chernobyl accident that is an honor received by only four other members of the Russian Academy of Sciences. Id. at 28. The District Court acknowledged that "[l]ikely more than other expert before the court, Professor Shevchenko has had extensive first-hand experience examining the effects of radiation exposure." 911 F.Supp. at 816.

Appendix A

Shevchenko's expert opinion testimony covered two distinct areas. The first area dealt with his morphological study of trees in the Three Mile Island area which he claims were damaged by radiation from the reactor accident, together with his radiation dose estimates based on the observed damage. The second area was his testimony about the substance of a cytogenetic analysis performed by a colleague, Dr. Galina Snigiryova, the head of the Cytogenetic Laboratory of the Moscow Institute of Diagnostic Surgery, on blood samples of a group of Three Mile Island area residents.[115] Based on Snigiryova's cytogenetic analysis, Shevchenko used a regression curve to arrive at radiation dose estimates. Each area of his proffered testimony is discussed separately.

b. Shevchenko's Tree Study.

Shevchenko's tree study is contained in an affidavit he prepared on July 6, 1994.[116] App. Vol. VI, at 4198-4211. In

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115. According to the Trial Plaintiffs' plan, Shevchenko was to testify not only about Snigiryova's cytogenetic analysis, but also about the tests and reports prepared by, inter alia, Gennady Kozubov and Olga Tarasenko, both of whom are scientists from the former Soviet Union and were apparently recruited by Shevchenko to provide expert reports. Trial Plaintiffs' Br. at 26-27. The District Court found that the substance of Snigiryova's report was within the area of Shevchenko's expertise and he was, therefore, permitted to testify about it. 911 F.Supp. at 811. However, the court found that the substance of Kozubov's and Tarasenko's tests and reports was outside the area of Shevchenko's expertise. Thus, he was not permitted to testify about their tests. Id. As it turned out, both Kozubov and Tarasenko were called as witnesses at the in limine hearings. Their testimony is discussed infra.

116. Shevchenko's Affidavit is captioned "Affidavit of Vladimir R. Shevchenko, Ph.D., Dr. Sc., Concerning the Dose to (Cont'd)

it, he states that he visited the Three Mile Island area for a three week stay beginning on June 18, 1994.[117] Id. at 4198. During that time, he conducted a morphological study of radiation-damaged trees in various areas around Three Mile Island. Id. In addition, Shevchenko met with James Gunckel and he and Gunckel conducted a joint study of radiation-damaged trees in the area. Id. Shevchenko and Gunckel "discussed in depth the possible causes" of the damage to the trees. Id.

The starting point of Shevchenko's tree study is his belief that there are several woody plants which can be used as long-term "indicators" of "relatively high exposures from radionuclide emissions." Id. at 4202. His belief is based on

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Any Individual from the TMI Unit Accident." In addition to discussing radiation-damaged trees, the affidavit contains a discussion of radiation sickness and disease allegedly suffered by TMI area residents, together with a discussion of radiation-induced illnesses and death suffered by animals in the TMI region. Further, the affidavit concludes with Shevchenko's dose estimates, not simply as to the trees he studied, but also as to the humans and animals in the TMI area. The district court did not mention the human and animal references in its analysis of this area of Shevchenko's expert testimony. Thus, we assume that the Trial Plaintiffs did not proffer Shevchenko as an expert competent to give testimony about dose estimates to humans. In addition, the Trial Plaintiffs' brief does not mention those aspects of Shevchenko's affidavit. Consequently, we assume that the focus of our inquiry is only on Shevchenko's tree study.

117. Shevchenko had a follow-up visit to the area in January of 1995. App. Vol. VI, at 4214.

his own studies of plants and trees in those areas of the former Soviet Union where there have been known radiation releases, and "definitive dose data from the Brookhaven Gama Field." Those woody plants are pine, spruce and maple trees. Id. at 4206.

According to Shevchenko, the most significant morphological change in the pine tree in response to a lethal exposure to ionizing radiation "is related to the death of the terminal bud in the main leader shoot." Id. at 4202.

> This change removes the apical dominance of the leader over the most apical 6 or 7 axillary buds when then formed short, multi-budded lateral branches and resulted in a tree with an easily identifiable, flat, bushy tree top.

Id. Shevchenko claims that spruce trees are more sensitive to radiation than pine and that exposure to high levels of ionizing radiation "causes death of all terminal buds," which "causes the tree top to look like a skeleton made of branches." Id. at 4203. At the dead top of the spruce tree, "lateral buds able to renew growth likely do not exist, so that it is easy to identify such trees visually." Id. In the maple tree,

> [t]he phloem companion cells on the inner bark are the most sensitive to ionizing radiation, their death being the cause of dead spots on the bark of the tree. This causes visible effects like lesions in the bark, large wounds on the tree trunks and the loss of bark. Maple trees die by indirect effect. Ionization of water by beta-rays will, depending

> on the dose, shatter the xylem, water-conducting vessels. When a maple tree dies following irradiation, it does so very gradually. First, the leaves in the center of the crown shrivel and die after one week. Next, the rest of the leaves develop anthocyanins, develop fall coloring within a few weeks, and then the leaves dehisce more or less normally but only after about 4-6 weeks. In the spring, shoots in the middle or lower part of the crown are slow to develop sparse leaves and lesions appear in the bark. Thus, the main indicators of radiation damage which can still be observed 15 years after the accident are wounds on the surface of the bark. Such wounds have a typical appearance and are easily identified. . . . Often such trees have dry branches and dry tops.

Id. at 4204-05.

In the course of his morphological tree study, Shevchenko "observed damaged spruce, pines and maples" and concluded that irradiation "is the cause of the full spectrum of the observed morphological anomalies." Id. at 4206. He opined:

> It is important that in some places which were affected by the radioactive cloud after the accident, simultaneous damage to spruce, pines and maples as well as to other trees was observed, which is evidence of ionizing radiation effects. The radiation damage to each tree is morphologically different — damage to top buds,

> dead tree tops, flat tree tops, bark wounds. The presence of a whole spectrum of tree damages in the same area and all with a very high frequency cannot be explained by anything but the effects of ionizing radiation exposure.

Id. Finally, he gave a dose estimate based on his observations of the tree damage. In his "professional opinion . . . the cases of tree damage . . . in the TMI region, based on results of my personal observations . . . , are related to the effects of ionizing radiation in doses of about 200 to 1,000 rem [2 Sv to 20 Sv]." Id. at 4211.

Initially, the District Court held that the tree study and the dose estimates were admissible. 911 F.Supp. at 816-817. Although the court conceded that the defendant's objection was well-founded, the court concluded that Shevchenko's experiences in studying first-hand the effects of ionizing radiation trumped any technical deficiencies in his methodology. The court wrote: "[W]hat his testimony may lack in rigid conforming to technical standards is amply counterbalanced by his extensive experience." Id. at 817.

Shevchenko's methodology was further attacked in a motion for reconsideration. Once again, the court conceded that the challenge to the methodology was "accurate and insightful." In re TMI Litigation Cases Consolidated II, 922 F.Supp. 997, 1014 (M.D.Pa.1996). Nonetheless, the District Court found that Shevchenko's expertise and experience were sufficient to overcome methodological deficiencies, primarily because the proffered testimony satisfied Rule 702's helpfulness or fit requirement. Id. The court found:

> Because of his first-hand experience, Professor Shevchenko's observations will be helpful to the trier of fact. Even if Professor Shevchenko were to do nothing more than to verify that he observed radiation damaged trees in the former Soviet Union, and note that the damage he saw in the TMI area was consistent with his observations of tree damage in the former Soviet Union, his testimony would assist the jury in determining whether it is more likely than not that the TMI area was contaminated during the TMI accident.

Id.

Shevchenko's dose estimates did not fare so well on reconsideration. In a nutshell, the court found that it was unable to determine Shevchenko's dose estimate methodology. The court wrote:

> The most certain thing that the court can say regarding the dose calculations derived from the tree study methodology is that after reading all of Professor Shevchenko's reports, deposition testimony, and the hearing transcripts, the court is unable to define the precise steps of his methodology. Each time Professor Shevchenko states his methodology Defendants challenge a component of that methodology and Professor Shevchenko alters the methodology to rebut the challenge. It is axiomatic that such methodological fluctuations are not scientific. . . . A purportedly scientific opinion that constantly

> changes merely to avoid critique can hardly be said to be based upon "good grounds."

Id. at 1015. Consequently, the court granted the motion for reconsideration insofar as it challenged dose estimates and excluded Shevchenko's proffered dose estimate testimony.

c. Discussion and Conclusions.

We are troubled by the District Court's exclusion of Shevchenko's dose estimate testimony based on its inability to determine Shevchenko's dose estimate methodology. The court found that Shevchenko could testify "as to the observations he made of damaged trees in the TMI area and to his comparison of the damage observed here with tree damage at radiation exposed sites in the former Soviet Union," Id. at 1015, but that he could not offer dose estimates based on his tree study. In other words, the court found that Shevchenko could testify that he found radiation damaged trees near TMI, but that he could not draw any conclusions as to the radiation dose which caused that damage.

As noted above, the court's reason for excluding Shevchenko's dose estimates was its stated inability to divine Shevchenko's dose estimate methodology. However, we do not believe that it is as difficult to determine that methodology as the District Court concluded. Shevchenko found three species of trees in the vicinity of TMI which he claims were damaged by ionizing radiation, and he then compared them with trees of the same species which he believes to have been damaged by ionizing radiation in the former Soviet Union. As noted above, those species are pine,

spruce and maple. At least with regard to pine and spruce, Shevchenko referred to studies of radiation damaged trees around Chernobyl where, presumably, dose exposures had been calculated. Shevchenko's affidavit noted that, as a result of the studies in the former Soviet Union, the "frequency of morphological anomalies of pines in the Chernobyl accident area was observed in 1986-1987 where exposures were from 200 -400 R (2.0 to 4.0 Gy)." App. Vol. VI at 4202. Additional studies in the Chernobyl area demonstrate that "the lethal dose" for spruce is about 1000 R (10 Gy), and "[e]xposure of 3.5 to 4.0 Gy causes death of all terminal buds of spruce trees." Id. at 4203.

Given that data, we can identify Shevchenko's dose estimate methodology. He simply compared the degree of damage to certain trees in the TMI area with the degree of damage to the same species of trees in the former Soviet Union. If the degree of morphological damage was similar, Shevchenko used the dose exposure estimates from the Soviet Union trees to deduct the dose exposure necessary to cause the similar morphological damage to the TMI area trees. Admittedly, Shevchenko's dose estimate methodology relies in part on his own ipse dixit, rather than on something more readily verifiable, and, in that regard, it is open to attack. See Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1315-16 (9th Cir.), cert. denied, 516 U.S. 869, 116 S.Ct. 189, 133 L.Ed.2d 126 (1995) ("[S]omething doesn't become 'scientific knowledge' just because it's uttered by a scientist; nor can an expert's self-serving assertion that his conclusions were 'derived by the scientific method' be deemed conclusive. . . ."). However, Shevchenko's

methodology also relies heavily on his "first-hand experience examining the effects of radiation exposure." 911 F.Supp. at 817. It is this first-hand experience which the District Court weighed heavily in favor of admitting Shevchenko's tree study. In our view, the dose estimate methodology is simply the next sequential step up from the tree study methodology. Inasmuch as the dose estimate methodology flows logically from the tree study methodology, we believe that the District Court's conclusion that the dose estimate methodology was based on inadequate methodology was inappropriate.

Similarly, to the extent that the District Court's exclusion of the dose estimates was based on the court's belief that Shevchenko's methodology changed in response to challenges, see 922 F.Supp. at 1014, the exclusion was also inappropriate. If Shevchenko's methodology did change to meet Daubert challenges, those changes strike at the heart of Shevchenko's credibility as a witness and the weight to be afforded his testimony. See Ambrosini v. Labarraque, 101 F.3d 129, 141 (D.C.Cir.1996) (District Court improperly conflated the questions of admissibility of expert testimony and the weight appropriately to be accorded such testimony by a fact finder).

Nonetheless, we do not believe that the court abused its discretion in excluding Shevchenko's dose estimates. Shevchenko's dose estimates suffer from the same infirmity as Gunckel's. Shevchenko's dose estimates are also extraordinarily high. They range from a low of 200 rem to a high of 1000 rem. As noted earlier, deterministic effects begin to occur at doses above 100 rem (1 Sv). See

CHERNOBYL, at 39.[118] The higher the dose estimates climb from the low of 200 rem to the high of 1000 rem, the closer Shevchenko's dose estimates approach a point where significant human casualties should have occurred from acute radiation syndrome.[119] That didn't happen. In short, even

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118. The Chernobyl PROJECT noted that deterministic effects begin above 100 rad (1 Gy). However, it also reported that "[f]or most practical applications, the radiation weighing factor is unity; that is, the numerical values for absorbed dose [rad] and equivalent dose [rem] will be equal." Chernobyl, at 21. That is especially true where gamma (<<gamma>>) radiation is alleged to be the source of the harm. The quality factor, Q, of gamma (<<gamma>>) radiation is 1. Thus, the absorbed dose and the equivalent dose of gamma (<<gamma>>) radiation will be equal. See p. 637- 38 supra. 119.

119. For example,

> [i]n the absorbed skin dose range of 2 to 7 GY (200 to 700 rad), the hematopoietic syndrome [a subgroup of acute radiation sickness] may be encountered. After the prodromal period, the duration of the asymptomatic latent period is 1 to 3 wks. The signs and symptoms result from radiation damage to the bone marrow, lymphatic organs, and immune response. In this syndrome, rapid reduction in the lymphocytes and a somewhat more delayed reduction of leukocytes, platelets, and red cells occur. The granulocytopenia leads to infection, and the thrombocytopenia leads to hemorrhage. Mean survival is usually 2 to 6 wks, with the nadir of the various blood elements occurring approximately 30 days after exposure. Death usually results from hemorrhage and infection.

MEDICAL EFFECTS, at 280.

though Shevchenko's dose estimate methodology may be reliable, his conclusions based on that methodology are not. A reliable methodology "cannot sanitize an otherwise untrustworthy conclusion." Heller, at 155.

d. The Cytogenetic Analysis.

As noted earlier, Galina Snigiryova[120] performed a cytogenetic[121] analysis on blood samples of a group of 29 Three Mile Island area residents.[122] According to Snigiryova, it is possible to evaluate absorbed radiation doses and to predict resulting biological effects of radiation exposure based on an analysis of the cytogenetic effects of ionizing radiation on human peripheral lymphocytes.[123] App. Vol. VI,

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120. Snigiryova's qualifications as an expert were not disputed. She has Ph.D. in Radiation Biology and, in addition to being the head of the Cytogenetic Laboratory of the Moscow Institute for Diagnostic and Surgery, she has carried out, inter alia, cytogenetic investigations on people exposed to ionizing radiation following the Chernobyl accident and on people irradiated as a result of nuclear weapons testing in the Semipalatinsk Nuclear Testing Grounds. Curriculum Vitae of Galina Snigiryova, App. Vol. VI, at 5102.

121. Cytogenetics is "[t]he branch of genetics concerned with the structure and function of the cell, especially the chromosomes." STEDMAN'S MEDICAL DICTIONARY 436 (26th ed.1995).

122. Snigiryova's report, captioned Cytogenetic Analysis of the People Living in the Neighborhood of TMI Nuclear Power Plant, is contained in Vol. VI of the Appendix at 5103-5117.

123. A lymphocyte is "[a] white blood cell formed in lymphatic tissue throughout the body. . . ." STEDMAN'S MEDICAL DICTIONARY 1008 (26th ed.1995).

at 5103. The cytogenetic method is based on an analysis of the frequency of chromosome aberrations in peripheral lymphocytes. Id. Snigiryova's cytogenetic study focused upon a chromosome aberration known as a dicentric.[124] Id.

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124. The Trial Plaintiffs have not provided us with an explanation of what a dicentric is. Consequently, we refer to the report of defendants' expert, Michael A. Bender, Ph.D., a Senior Scientist in the Medical Department of the Brookhaven National Laboratory, who has studied chromosome aberrations for 38 years and has "participated in the development, verification, and application of biological radiation dosimetry using aberrations in lymphocytes form human peripheral blood samples since 1961." App. Vol. XII, at 9961. Dr. Bender's report states:

> Chromosomal aberrations are generally studied in cell divisions, during which the chromosomes are visible in the ordinary optical microscope. When such divisions of peripheral lymphocytes, called mitoses, are examined it is possible to enumerate aberrations of various kinds. In mitosis each chromosome, of which there are normally 46 in human cells, appears as a double linear structure with parallel "chromatids," which will become daughter chromosomes after cell division is completed, still attached at a point along their length called the centromere. Generally speaking, prior to its replication before cell division each chromosome behaves as a single linear structure. If the chromosome is broken and/or rearranged prior to replication, what are termed "chromosome type" aberrations result. These affect both chromatids of the chromosome (as a result of replication of the aberrant linear structure to form daughter chromosomes). If breaks and/or rearrangements occur after chromosome replication, however, the individual chromatids behave independently, with (one trivial

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at 5109. A high frequency of dicentrics is indicative of radiation exposure. Id. at 5109.

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> exception) breaks and/or rearrangements affecting only one of the two parallel chromatids. These are called "chromatid type" aberrations.
>
> Because human peripheral lymphocytes are all in a pre-replication stage of the cell cycle while in the circulation, their irradiation when in the body results only in aberrations of the chromosome type when they are later caused it divide in vitro for cytogenetic examination; no chromatid type aberrations are induced. Thus only chromosome aberrations are useful as indicators of human radiation exposure.
>
> Aberrations of either the chromatid or the chromosome type may be simple chromosome breaks, resulting in a shortened chromosome or chromatid and a fragment lacking a centromere (an acentric fragment), or be the result of intrachanges or interchanges between two or more breaks in the same or different chromosomes. If of the chromosome type, two break exchanges may either be what cytogeneticists call "symmetrical," including translocations and inversions, or "asymmetrical," including dicentric and ring chromosomes. The latter are what are generally used for cytogenetic dosimetry, mainly because their topology is radically different from that of normal chromosomes, so that they are easily and efficiently detected. A dicentric, as the name implies, has two centromeres instead of the normal one, while a ring lacks any ends.

App. Vol. XII, at 20-22.

Appendix A

The residents whose blood samples were drawn for the cytogenetic analysis were selected by counsel for the plaintiffs; presumably based on criteria proposed by Shevchenko. App. Vol. VI, at 4978. The blood was drawn on two separate occasions in 1994 and 1995, and shipped to Snigiryova in Russia. Snigiryova made short-term peripheral blood cultures, fixed and stained them according to standard procedures and examined the resulting slides for chromosomal aberrations. Id. at 5103-5104.

She then counted the dicentrics in the blood samples. Of the 29 people whose blood was subjected to the cytogenetic analysis, she found that 22 had "[q]uantitative and structural changes in a cell chromosome system." Id. at 5112. She also found dicentrics in 19 people and found one cell with a three centric in one person. Id. Snigiryova concluded that the average frequency of dicentrics was .2 per 100 cells, which was ten times higher that the control value she used of 2 dicentrics per 10,000 cells examined, obtained from a study of individuals who lived in Moscow. Id. at 5110. Based on her cytogenetic analysis, Snigiryova opined that the group of TMI residents whose blood she analyzed were exposed to ionizing radiation from the TMI reactor accident. Id. at 5112.

Snigiryova's cytogenetic analysis was contained in her written report. She did not testify at an in limine hearing after the admissibility of her report was challenged. Instead, over objection, the District Court permitted Shevchenko to offer an opinion as to Snigiryova's analysis because it found that cytogenetic analysis was within Shevchenko's area of expertise. 911 F.Supp. at 811.

Appendix A

Snigiryova's written report does not contain a dose estimate based on her dicentric enumeration. However, Shevchenko did make a dose estimate based on Snigiryova's dicentric counts. Using a "calibration curve," Shevchenko calculated that the dose exposures among the TMI group which was the subject of the cytogenetic analysis ranged from 60 to 80 rems [0.6 to 0.8 Sv] for someone with 2 dicentrics per 500 cells, to 90 to 120 rems [0.9 to 1.2 Sv] for someone with 3 dicentrics per 500 cells, and 120 to 200 rems [1.2 to 2 Sv] for someone with 5 dicentrics per 500 cells. App. Vol. VI, at 4220.

Initially, the District Court rejected the attempt to preclude the cytogenetic study and Shevchenko's dose estimates, holding, as it did with Shevchenko's tree study, that Shevchenko's extensive experience "counterbalanced" whatever his testimony lacked "in rigid conformity to technical standards." 911 F.Supp. at 817. However, on a motion for reconsideration, the court found that Shevchenko's methodology of arriving at dose estimates based on Snigiryova's cytogenetic analysis was unreliable because too long a period of time expired between the alleged exposure and the analysis. Id. at 1013. Consequently, the District Court granted the motion to reconsider with respect to Shevchenko's dose estimates and prohibited him from estimating dose based upon Snigiryova's cytogenetic study. Id. However, the court denied the motion with respect to the cytogenetic analysis. It held that Shevchenko could testify as to the substance of the cytogenetic analysis and to the findings regarding the presence or absence of chromosome aberrations. Id.

e. Discussion and Conclusions.

The District Court's exclusion of Shevchenko's dose estimates based on Snigiryova's cytogenetic study presents us with a difficult question. It is undisputed that "[a] chromosome aberration occurs when cells are irradiated and the chromosomes are broken and can rejoin with time after exposure." RADIATION DOSE RECONSTRUCTION, at 52. In fact, the enumeration of unstable chromosome aberrations is "among the most sensitive markers for radiation exposure." Id. at 59. Moreover, counting the number of dicentrics is an accepted method, not simply for determining if the subject of the analysis was irradiated, but also for estimating radiation dose to the individual.

> Chromosome aberrations induced in . . . human lymphocytes have been the system of choice for a biologic dosimeter used to quantify the dose to which an individual has been exposed or to verify or corroborate a suspected dose exposure for which no physical dose measurements have been available. These studies used mainly a dicentric aberration. . . .

Id. (emphasis added); see also MEDICAL EFFECTS, at 55 ("Dicentrics are an important biologic dosimeter."). The enumeration of chromosome aberrations can be used to estimate doses as low as 0.10 Gy [10 rad].[125] Id. at 53.

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125. At lower doses and lower dose rates, the enumeration of chromosome aberrations is unlikely to help with dose reconstruction. RADIATION DOSE RECONSTRUCTION, at 60.

However, dicentrics are unstable chromosome aberrations whose frequency deceases with time after exposure. RADIATION DOSE RECONSTRUCTION, at 52. Consequently, if unstable chromosome aberrations are "measured within a year after acute exposure there will be little decay and the sensitivity will allow it to serve as a good dosimeter." Id. at 59. However, the reliability of this indicator decreases over time. Thus, the farther away in time from the alleged exposure, the less useful the dicentric enumeration will be as an indicator of radiation exposure and the foundation for a dose estimate. See Id. at 53 ("It must be kept in mind that the decay found in this end point makes it useful only for an individual recently exposed to radiation. Authors have reported values for the average disappearance half-time of lymphocytes containing dicentric and centric rings ranging from 130 days . . . to 3 years. . . ."). To circumvent the problem inherent in using a dicentric enumeration as a method for estimating dose exposure, stable chromosome aberrations, and more precisely, translocations,[126] are now being used as markers for radiation exposure. Id. at 59 ("The disadvantages associated with unstable markers are avoided when stable markers, such as reciprocal translocations, . . . are used."). Translocations are measured by a process called the "FISH" (Fluorescent In Situ Hybridization)[127] method and "[v]alidation

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126. See p. 688-89 n. 124, supra.

127. The FISH method is also known as "chromosome painting" and is described as follows:

> In this technique, the DNA is thermally denatured to provide single strands of DNA. These targeted strands

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measurements made by [the FISH method] have shown that the frequency of reciprocal translocations in whole-body-exposed individuals is constant with time after exposure." Id. at 60.

Here, Snigiryova's dicentric count was done 15 years after the alleged exposure. Since dicentrics disappear over time, the usefulness of her dicentric enumerations as a basis to make dose estimates is open to question. She estimated in her report that dicentrics eliminate at the rate of approximately fifty percent per year and that cells with chromosome aberrations eliminate at a rate of approximately fifty percent in three years. App. Vol. VI, at 5110-11. She conceded, not only that the use of her dicentric enumeration for dose estimation was problematic, but also that the enumeration of stable chromosome aberrations using the FISH method was the preferable methodology. Her report states:

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> are incubated with nontarget DNA probes that bind to the DNA sequences that are homologous. The target DNA is stained, and the nontarget DNA is counter stained. Under a fluorescence microscope the target DNA appears yellow, and the nontarget DNA appears red. In the case of a translocation, the affected DNA strand will appear to be partially red and partially yellow. This method detects only a fraction of the translocations, so that it is necessary to apply a multiplication factor to estimate total translocation frequency.

MEDICAL EFFECTS, at 65.

Appendix A

> The problem of the estimation of dose radiation using the cytogenetic data is very problematically (sic) in this situation. Firstly, this is connected with the long period after TMI accident. In such situation it seems necessary to estimate stable chromosome aberrations in lymphocytes of peripheral blood, using FISH method. . . . Analysis of stable chromosome aberrations is more important in such situations because translocations owing to their special structure may go through mitosis without complication. It is to allow to find stable chromosome aberrations a long period after irradiation and their frequency will not change.

Id. at 5111. Shevchenko admitted in his deposition that the FISH method was the preferable methodology upon which to base a dose estimate for the TMI residents who were the subject of Snigiryova's dicentric enumeration due to the length of time between the alleged exposure and the enumeration. Id. at 4585.

Nonetheless, the Trial Plaintiffs claim that Shevchenko can make a reliable dose estimate using a dicentric enumeration on the basis of a regression analysis. His regression analysis is nothing more than a multiplication of the total number of dicentrics enumerated by Snigiryova to arrive at the higher number of dicentrics presumably existing after exposure as a result of the reactor accident. Id. at 4220. Of course, in the regression analysis, the multiplier is the crucial variable. Snigiryova and Shevchenko both opined that the frequency of dicentrics to translocations observed soon

after irradiation is equal. See Id. at 5111 (Snigiryova: "According to some data the frequencies of unstable (dicentrics, centric rings and acentric fragments) and stable (translocations) aberrations observing after irradiation are about equal.") and Id. at 4794 (Shevchenko: "The original frequency under the effect of radiation is the same, one to one ratio has been shown."). Consequently, because of the equality of frequency of dicentrics to translocations at the time of initial irradiation, a correlation between unstable dicentrics and stable translocations can be developed and from that correlation a ratio can be determined. That ratio can be used to develop the multiplier in the regression analysis.

The ratio of dicentrics to translocations at the time of the analysis is crucial to developing the correct multiplier. Nevertheless, Snigiryova's cytogenetic analysis focused solely on dicentrics and not on translocations. The number of translocations in the chromosomes of the TMI residents who were the subject of the analysis is an unknown. Therefore, neither a ratio nor a multiplier can be developed, and without that ratio, there can be no reliable dose estimate. Shevchenko admitted as much in a report, dated February 4, 1996. That report states a "ratio of translocation frequency to dicentric frequency . . . must be used in order to reconstruct the TMI doses using dicentrics." Id. at 4342. Shevchenko admitted at the time he made his dose estimate that there was no established ratio between dicentrics and translocations for the group studied by Snigiryova. In his February 21, 1995, report, he wrote: "Unfortunately so far we don't know a ratio between stable and unstable chromosome aberrations for persons suffered from the TMI accident." Id. at 4220.

Nonetheless, despite his admission that the ratio of translocations to dicentrics was unknown when he made his dose estimate, Shevchenko estimated a dose range between 60 to 200 rem based on a multiplier of 6-8. Id. at 4220. His admission that he did not know a translocation/dicentric ratio at the time he made his dose estimate, effectively negated the reliability of the dose estimate. Furthermore, Shevchenko changed his multiplier over time from 6-8 in his February 21, 1995, written report, Id. at 422, to 5 at the in limine hearing on November 22, 1995, Id. at 4811, to 2-3 in a March 4, 1996, written report, Id. at 4357. However, he never explained why he changed the multiplier; and he never made a corresponding change in his dose estimate despite the changing multiplier. Consequently, determining what, if any role, his regression analysis occupied in his dicentric dose estimate methodology is problematic.

Earlier, we wrote that the District Court's exclusion of Shevchenko's dose estimate presented us with a difficult question. Radiation dose estimation based on dicentric enumeration is a valid and reliable scientific methodology, but the validity and reliability decrease as the time gap between the alleged irradiation and the dicentric count increases Accordingly, the fifteen year delay between the alleged irradiation and the dicentric count here is a factor that must be considered in determining the continued validity of Shevchenko's dose estimate based on Snigiryova's dicentric count. As noted earlier, Daubert does not require that the proffered expert is correct. Paoli II, at 744. Rather, the proponent of the challenged testimony need only demonstrate that their opinions are reliable. So long as the expert's testimony rests upon

> "good grounds", it should be tested by the adversary process — competing expert testimony and active cross-examination — rather than excluded from juror's scrutiny for fear that they will not grasp its complexities or satisfactory weigh its inadequacies.

Ruiz-Troche, at 85 (citing Daubert, at 596, 113 S.Ct. 2786). Thus, if the only evidentiary hurdle was the fifteen year gap between the alleged irradiation and the dicentric enumeration, Shevchenko's dose estimate could, arguably, survive Daubert/Paoli II scrutiny.

Here, however, both Snigiryova and Shevchenko conceded the FISH method is the reliable methodology for dose estimation where there is a long span between exposure and the cytogenetic study. In her report, Snigiryova wrote:

> The problem of the estimation of dose estimation using the cytogenetic data is very problematically in this situation. Firstly, this is connected with a long period after the TMI accident. In such situation it seems necessary to estimate stable chromosome aberrations in lymphocytes of peripheral blood, using FISH method (fluorescence in situ hybridization).

App. Vol. VI, at 5111 (emphasis added). And, at his deposition, Shevchenko was asked about this statement at his deposition. The following exchange occurred:

> Q: Do you agree with that statement?

> A: Yes. I was just trying to show that that's how the situation is and I was trying to show what the problem is.

Id. at 4585. Furthermore, Shevchenko admitted that a known dicentric/translocation ratio for the TMI group must be used to estimate dose using a dicentric enumeration. As noted above, the delay here was 15 years. Given that delay and Shevchenko's concessions, we can not say the District Court abused its discretion in excluding Shevchenko's dose estimates under the court's Daubert/Paoli II analysis.

v. Gennady Kozubov.

a. Qualifications.

Gennady Kozubov is a forestry engineer with a Doctor of Biological Sciences degree. App. Vol. VI, at 5156-57. He is the Chief Scientific Worker-Advisor at the Institute of Biology, Komi Science Center — Ural Division, Russian Academy of Science. Id. at 5124. His area of expertise is dendrology, which he defined as the "science of trees including the systematics and morphology of woody plants." Id. at 5158. Since 1986, he has studied the effects of the Chernobyl accident on woody plants. Kozubov believes that a dendrometric analysis of the growth rings of trees can determine if the trees were damaged by irradiation and a dose estimate can be inferred from that damage. Kozubov performed a dendrometric analysis on wood core borings obtained from the area around Three Mile Island.[128]

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128. He testified that he received a patent from the former Soviet Union to develop this dendrometric analysis technique. Id. at 5181.

Appendix A

b. Kozubov's Opinion.

In his written report, Kozubov relied upon his study of irradiated trees in the Chernobyl area to conclude that radiation at high levels can suppress the annual growth of tree rings and that radiation at low levels can stimulate that growth. Id. at 5126-28. Although he indicated that tree ring growth is dependent upon a number of other factors, including precipitation, temperature, sunlight and mineral nutrition, Kozubov opined that if a large enough sample of trees of the same species, growing under identical conditions except for exposure to radiation, is examined, then the differences in their annual growth rings can be used to infer the doses the trees were exposed to. Id. at 5126-28.

Kozubov received wood boring samples that Shevchenko collected from the area surrounding Three Mile Island in 1995. Id. at 5128. The samples were "mostly 2 samples" from each of 35 spruce trees and 14 pine trees, which Shevchenko collected at a height of 1.2 to 1.5 meters. Id. He also received 9 pine and 13 spruce samples from Shevchenko to use as a control group. Id. at 5131.

When Kozubov received the samples he polished them so that the annual growth rings were clearly visible. Id. at 5168. Where polishing did not clearly reveal the annual rings, special equipment was used to enhance the visibility of the rings. Id. The samples were observed under a measuring microscope, starting "at the bark and going deep into the center," and the thickness of the annual rings from 1974 to 1985 was measured. Id. All of the indicators of ring growth were entered into a computer, average statistical data were

calculated, and a graph was constructed. Id. at 5169. Absorbed doses were then calculated on the basis of the formula which Kozubov developed in connection with a patent he received for his dendrometric analysis technique.

Applying this dendrometric analysis, Kozubov concluded that (1) the spruce samples showed a "distinct inhibition of annual wood increment" in 1979, and a "stimulation" in 1980, and thus were irradiated;[129] (2) radiation doses ranged from 0.5/0.6 to 1.9/2.0 Gy [50/60 to 190/200 rad]; (3) the irradiated trees were located mainly west and northwest of the TMI reactor; and (4) his conclusions are "trustworthy" because the samples subjected to the dendrometric analysis were compared to the control group. Id. at 5137.

The defendants challenged Kozubov's opinion claiming that he did not follow the requirements of his own methodology. After an in limine hearing, the District Court found that his dendrometric analysis methodology was reliable. In re TMI Litigation Cases Consolidated II, 910 F.Supp. 200, 203 (M.D.Pa.1996). However, the court excluded Kozubov's proffered testimony and his dendrometric analysis because it did not " 'fit' within the litigation." Id. At the in limine hearing, Kozubov testified that his dendrometric analysis, standing alone, would not prove that the samples were irradiated. It had to be correlated with a study of seeds, needle growth and wilting processes of the leading shoots of the trees to confirm the conclusions

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129. Kozubov's report recites that he was unable to perform the dendrometric analysis on the pine samples. The reason he could not do so is unclear. App. Vol. VI, at 5132.

of the analysis. However, no such correlation was undertaken. Consequently, based in large part upon Kozubov's own concession as to the absence of critical correlation the court held that Kozubov's testimony and his dendrometric analysis would not assist the jury "in determining whether or not persons (and trees) in the TMI area at the time of the accident were exposed to radiation." Id.

c. Discussion and Conclusions.

Kozubov's admission that the dendrometric analysis would not by itself permit him to conclude that growth ring variations were caused by irradiation seriously undermines his opinion that the TMI tree samples were irradiated as well as the reliability of his dose estimates. As a result of his work after Chernobyl, he testified that he discovered that tree growth becomes chaotic after irradiation, id. at 5203, presumably because irradiation changes the metabolism of the trees. Id. The deviations caused by irradiation can be observed in seeds, needle growth, and wilting processes. Id. at 5204. Consequently, and presumably to exclude other causes of observed variations in tree ring growth, Kozubov's dendrometric analysis methodology requires correlation. He testified:

> [W]e always say that [the dendrometric] method is only used with other methods. One cannot use just one method to give this estimate.
>
> That's why in Chernobyl, we also studied the needle growth, also we studied growth patterns, seeds and also the wilting process of the leading

> shoots. That's why our estimations had a compound picture. If we use only this one [dendrometric] method, of course we will not say that this was caused by exposure.

Id. at 5204. But, no studies of seeds, etc. were done by Kozubov or anyone else[130] to confirm the accuracy of the dendrometric analysis and the dose estimates for the accident at Three Mile Island.

The District Court found that the missing correlation went to the helpfulness or fit requirement of Rule 702. However, we believe that the missing correlation affected the essential reliability of the methodology itself rather than its "fit," because correlation is an essential element of the dendrometric analysis. The failure to correlate renders the methodology unreliable and the District Court therefore correctly concluded that the expert's testimony was inadmissible. Paoli II, at 745 ("[A]ny step that renders the analysis unreliable under the Daubert factors renders the expert's testimony inadmissible. This is true whether the step completely changes a reliable methodology or merely misapplies that methodology.").

Moreover, the failure to correlate was not the only misapplication of the methodology. In Kozubov's formula

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130. The Trial Plaintiffs suggest that Kozubov did not need to perform the studies to confirm his dendrometric analysis because he could rely on Shevchenko's and Gunckel's morphological tree studies to supply the missing correlation. Trial Plaintiffs' Br. at 38. However, they do not provide any record citations which show that either Shevchenko or Gunckel made a study of seeds, needles or wilting processes.

for estimating doses, the coefficient of accordance, "C", is a critical variable which is derived by measuring tree ring increments following a known dose exposure. App. Vol. VI, at 5128. In his report, Kozubov recited coefficients of accordance for trees irradiated as a result of the Chernobyl accident. Id. Those coefficients were determined at Chernobyl by using radiation doses which were known and measured by TLD readings. Id. at 4614. However, in a follow up report written after his initial report, Kozubov wrote that the dose estimation formula "had a number of restrictions, as applied to the TMI accident." Id. at 5139. Significantly, he admitted that he did not have a coefficient of accordance for the trees he examined from TMI.

> First of all, is the lack of reliable evidence on the reaction of the native species of trees to the radiation exposure, the impossibility of experimental estimation of the coefficient of accordance "C".

Id.

But, the lack of the coefficient of accordance makes the entire dose estimation formula unworkable. Without a coefficient of accordance, the methodology cannot produce any dose estimate, let alone a reliable dose estimate. Thus, Kozubov's admitted inability to arrive at a coefficient of accordance constitutes a failure of the methodology.

We agree that Kozubov's proffered testimony should be excluded, but our reasoning differs from that of the District Court. Inasmuch as our differing viewpoints is rooted in

different interpretations of Rule 702, we exercise plenary review over the District Court's interpretation of Rule 702. See Paoli II, at 749. However, here, we end up in the same place as the District Court. We merely take a different route. However, both routes result in the exclusion of Kozubov's testimony, and we will therefore affirm the District Court's result as to Kozubov.

vi. Olga Tarasenko.

a. Qualifications.

Olga Tarasenko is a medical doctor who has a Ph.D. in immunology,[131] and is the head of the Immuno-Diagnostic Laboratory at the Russian Center of Molecular Diagnostic and Medical Treatment. She participated in the study of people exposed to ionizing radiation from nuclear weapons testing at the Semipalatinsk Nuclear Testing Grounds, and Trial Plaintiffs wanted her to testify about the results of an immunological study that she performed on blood samples of 19 residents of the Three Mile Island area.

b. Tarasenko's Opinion.

Tarasenko performed a comparative immunological study on blood samples from 5 groups of individuals. App. Vol. VI at 5209. The five groups were: (1) 19 people allegedly subjected to ionizing radiation as a result of the

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131. Immunology is "[t]he science concerned with the various phenomena of immunity, induced sensitivity and allergy." STEDMAN'S MEDICAL DICTIONARY 856 (26th ed.1995).

TMI reactor accident;[132] (2) a group of irradiated people who participated in the clean-up following the Chernobyl nuclear power plant accident;[133] (3) a control group from Moscow; (4) a group of inhabitants of Muslumovo village in the South Ural region of Russia exposed to ionizing radiation as a result of the Kyshtym accident;[134] and (5) a group of inhabitants of a "clean" village in the Altai region of the former Soviet Union. Id. Her study was an attempt to determine whether the TMI area residents exhibited immune system depression, and if they did, to compare their immune system parameters with the immune parameters of people in the former Soviet Union who were exposed to known levels of ionizing radiation. Her findings, contained in her written report, were as follows:

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132. Tarasenko performed her study at the request of Shevchenko and Snigiryova. The blood samples Tarasenko analyzed were taken from the same TMI area residents whose blood Snigiryova subjected to her cytogenetic analysis. App. Vol. VI, at 5305.

133. The Russian word for the people who were involved in the clean-up in the aftermath of the Chernobyl accident translates into English as "Liquidators." App. Vol. VI, at 4220. Tarasenko testified that, with one exception, the Liquidators whose blood she analyzed were exposed to approximately 25 rems [0.25 Sv] of ionizing radiation. Id. at 5299.

134. Muslumovo village is located in the area where a nuclear accident occurred in 1957 at the Mayak military plant which produced atomic weapons. The Mayak military plant was located near the city of Kyshtym. That area is referred to as the Eastern Ural Radiation Belt. App. Vol. VI, at 4199-20; 5209. According to Tarasenko, the Muslumovo residents were exposed to levels of ionizing radiation reaching 100 rems [1 Sv]. Id. at 510.

Appendix A

> In [the TMI group] even average characters substantially differ not only from generally accepted levels on immuno competent cells but from the levels obtained in control groups (Moscow and Altai inhabitants). . . .
>
> A sharp disbalance of immunoregulating cells was revealed. This disbalance in combination with the disturbances mention above evidences the presence of mixed immunodeficite (sic) status in the [TMI group].
>
> Such disturbances are observed in the patients who use immunodepressants (widely used antibiotics, aspirin and other medicines can be referred to this group of chemicals) and suffer from cancer, autoimmune diseases, syndrome (sic) of chronic weariness and others. It is undoubtedly necessary to carry out a dynamic examination of all persons in [the TMI group], regular observation of their immune status, medical and prophylactic measures.

Id. at 5209-10. Her written report does not discuss the possibility or probability that the mixed immunodeficit status of the TMI area residents was caused by exposure to ionizing radiation. She testified that when she did the comparative study, her purpose was not "to interpret these results." Id. at 5375. Rather, "it was[her] purpose to obtain this data, to record these results." Id.

However, after her opinion was challenged,[135] Tarasenko testified at the in limine hearing that the TMI area residents' immune system deficits that her written report associated with the use of immunodepressents, etc., are possibly the result of radiation exposure. Id. at 5308. She explained as follows:

> The conclusion is this, characteristics that we have determined for inhabitants in the area of Three Mile Island, they are hardly different, show almost no differences or — well, there is not quite an equivalent sign, but almost, almost the same as characteristics found for the inhabitants of Muslumovo village. . . .
>
> In other words, our conclusion is this, changes that we see in inhabitants of the Three Mile Island region are even deeper than in those who lived in that village and were eradicated (sic) as a consequence of the Kyshtym accident.
>
> * * *
>
> Our conclusion is that the immunodepression was found in both these groups under comparison. TMI group and Muslumovo group, immunodepression was present. The extent of immunodepression, however, was more prominent in the Three Mile Island accident.

Id. at 5312-13; 5320.

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135. Tarasenko's qualifications as an expert were not disputed.

Tarasenko testified that she was able to offer an opinion that the immunodepression that she found in the TMI area residents could have been radiation induced because after she provided her written report to Shevchenko, she received "information [from Shevchenko that] allowed me to rule out those other causes that are listed in the last paragraph of the report." Id. at 5309. The information she received was the summaries of the health histories of the 19 Three Mile Island area residents whose blood she examined. Those summaries were contained in Snigiryova's report of her cytogenetic analysis. Id. at 5377.

The District Court excluded Tarasenko's proffered comparative immunological study in its entirety not under Daubert/Paoli II, but under Rule 703. The court concluded that she "lacked the foundation to make the judgments she did." In re TMI Litigation Cases Consolidated II, 922 F.Supp. 997, 1024 (M.D.Pa.1996). Consequently, the court held that Tarasenko's "conclusions are not based upon 'good grounds' and are not scientifically reliable." Id.

c. Discussion and Conclusions.

Although the "primary locus" of the District Court's gatekeeping role is Rule 702, a court "should also be mindful of other applicable rules," Daubert, at 590; 595, 113 S.Ct. 2786, when conducting a Daubert analysis. Rule 703 provides:

> The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert

> at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.

Fed.R.Evid. 703.

Rule 703 thus focuses on the data underlying the expert's opinion. Paoli II, at 747. It permits experts to rely on hearsay so long as that hearsay is of the kind normally employed by experts in the field. Id. (quoting In re "Agent Orange" Product Liability Litigation, 611 F.Supp. 1223, 1245 (E.D.N.Y.1985)). Therefore,

> when a trial judge analyzes whether an expert's data is of a type reasonably relied on by experts in the field, he or she should assess whether there are good grounds to rely on this data to draw the conclusion reached by the expert.

Id. at 749. If the data underlying the expert's opinion are so unreliable that no reasonable expert could base an opinion on them, the opinion resting on that data must be excluded. Id. at 748. The key inquiry is reasonable reliance and that inquiry dictates that the "trial judge must conduct an independent evaluation into reasonableness." Id. Rule 703's reliability standard is similar to Rule 702's reliability requirement, i.e., "there must be good grounds on which to find the data reliable." Id.

The Trial Plaintiffs claim that the information Tarasenko received from Shevchenko was the medical history

summaries of the 19 people whose blood was the subject of her immunological study. While admitting that the information consisted of incomplete summaries, not complete hospital or medical records, the Trial Plaintiffs claim that the summaries contained a considerable amount of reliable information that Tarasenko could reasonably use to rule out the other causes of immunodepression noted in her written report, and thus allow her to conclude that the immunodepression was caused by ionizing radiation. They point to Tarasenko's testimony that the summaries included information regarding

> presence or absence of autoimmune diseases . . . [the] presence or absence of oncological cancer diseases, whether [the person] was a smoker or nonsmoker, and if he was a smoker what was the extent of smoking, then [the person's age], then a list of major diseases, as well as complaints.

App. Vol. VI, at 5375-77.

These summaries were the only information that Tarasenko had about the health histories of the people whose blood she examined. Id. at 5377; 5383. Although Tarasenko received these summaries from Shevchenko, they were not made by Shevchenko, nor were they based on medical or hospital records. Instead, the summaries were made by employees of Trial Plaintiffs' counsel, and they were based on interviews those employees had with the people whose blood samples were taken for Snigiryova's cytogenetic analysis. Id. at 4576. Apparently, the interviews were based

upon questions formulated by Shevchenko. Id.[136] Nonetheless, the summaries were made for litigation, not for the purpose of obtaining medical treatment. There is nothing improper about a medical report prepared solely for litigation. Paoli II, at 762. However,

> a physician who evaluates a patient in preparation for litigation should seek more than a patient's self-report of symptoms or illness and hence should either examine the patient or review the patient's medical records simply to determine that a patient is ill and what illness that patient has contracted.

Id. In Paoli II we concluded that where the physician who had been retained strictly for litigation purposes based pathological causation on nothing more than a plaintiff's self-report of an illness, the District Court's exclusion of the resulting evidence did not constitute an abuse of discretion. Common sense alone suggests that such evidence is "based on an unreliable source of information." Id.

That rationale applies here. The medical history summaries generated by the interviews for submission to Trial Plaintiffs' expert witnesses were unreliable and Tarasenko did not have good grounds to rely on them to arrive at her conclusion that the immunodepression her comparative study revealed was caused by ionizing radiation. Tarasenko should have done more. She should have either reviewed

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136. At his deposition, Shevchenko testified that "[a]t the moment when the blood was taken, the information was taken from the participants according to my scheme."

her study subjects' medical and hospital records or examined the subjects herself. See Id. ("[G]enerally, a doctor needs one reliable source of information showing that the plaintiff is ill and either a physical examination or medical records will suffice — but the doctor does need at least one of these sources."). She cannot rely on medical summaries prepared from interviews conducted by nonprofessionals as Tarasenko did here. This is especially true when the nonprofessionals are aligned with counsel for one of the litigants. In fact, in Tarasenko's initial report, she said that in order to arrive at an opinion as to the cause of the immunodepression, it is "undoubtedly necessary to carry out a dynamic examination of all persons [in the TMI group], regular observation of their immune status, medical and prophylactic measures." App. Vol. VI, at 5210. We agree. Tarasenko's own report thus demonstrates that the data supporting her challenged opinion were not reliable, and the District Court did not abuse its discretion in excluding her testimony.

vii. Bruce Molholt.

a. Qualifications.

Bruce Molholt earned a B.A. in mathematics from Hendrix College, a M.S. in microbiology from the University of Arkansas School of Medicine and a Ph.D. in microbiology from Indiana University. He did post-doctoral work in molecular biology and genetics at the University of Stockholm in Sweden, the University of Ghent in Belgium, and the University of Heidelberg in Germany. He taught immunology at the University of Kansas from 1960 to 1972 and at the Medical College of Wisconsin from 1976 to 1978.

He was a Super fund toxicologist with the Environmental Protection Agency from 1984 to 1988. He has been a Visiting Professor in the Environmental Studies Program at the University of Pennsylvania since 1988. In addition, he is a principal in, and the Program Director of, Risk Assessment and Toxicology at Environment Research Management, Inc. App. Vol. VII, at 5412-5413.

The Trial Plaintiffs characterized Molholt as an expert in two separate areas — toxicology[137] and risk assessment.[138]

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137. Molholt defined a "toxicologist" as "a scientist who evaluates the relationship between exposure to potentially hazardous substances and the onset of certain diseases." App. Vol. VII, at 6336.

138. Molholt defined "risk assessment" as follows:

> Whereas toxicology is qualitative, that is, does a certain substance have an inherent property which can cause disease, risk assessment takes it one step further. It attempts to quantify that relationship. That is, how much exposure to a toxic substance will cause disease; or if a disease is present, could this have been due to a given exposure to toxic substances knowing the amount of exposure.

App. Vol. VII, at 6336. To illustrate the difference between toxicology and risk assessment, Molholt offered the following:

> [T]oxicology is saying that if you are exposed to arsenic, you may develop mental insufficiency. If you are exposed to trichloroethylene, you may suffer liver damage. That is the discipline of toxicology.

(Cont'd)

He was proffered to render opinions as to dose exposure and medical causation.[139] Id. at 42.

b. Molholt's Opinions.

Molholt's first report (which the Trial Plaintiffs' characterize as his "Dose Exposure Report") was dated April 8, 1993. It is in the form of an affidavit and is untitled. Id. at 5424-5433. In it, Molholt opined that "[l]ymphocyte depression is the major sequela of radiation exposure," and therefore, "the pattern of depressed lymphocyte production . . . may be used as a long-lived form of human dosimetry[140]

(Cont'd)

> Risk assessment takes arsenic and says you must be exposed to ten milligrams per kilogram of soil for ten days, then you are at risk for these central nervous system difficulties. . . . [Risk assessment] tends to quantify not only what the level of exposure that is required for the onset of a certain disease, but then you are at risk for that disease with a hundred percent assurance, fifty percent assurance.
>
> Or in the carcinogenic realm, a whole different paradigm. And that is, if you are at risk from a certain exposure, what is your individual probability of risk put in a probabilistic formula.

Id. at 6344-45.

139. Molholt's expertise as a toxicologist and a risk assessor were not disputed.

140. Dosimetry is "the science of determining radiation fields and dose to individuals, or materials, by using any and all known types of detectors and calculational techniques." President's Commission, Report of the Task Force Group on Health Physics and Dosimetry 36 (1979).

to back-calculate the intensity of population exposures during radiation exposures such as occurred during the TMI accident." Id. at 5424-25. He noted reports by other authors that "[d]irect measurements of circulating lymphocyte levels in blood samples withdrawn from TMI area residents confirm that they suffered statistically significant lymphocyte depression following the accident." Id. at 5428. He also noted additional reports that "TMI area residents were found to have profound lymphocyte depression five years following the 1979 reactor accident." Id. at 5429. Using his back-calculation technique, Molholt concluded that "the immunological evidence supports the conclusion that human radiation exposures exceeded 100 rems [1 Sv] as a result of the TMI accident." Id.

Molholt's April 8, 1993, report was challenged under Daubert, but Trial Plaintiffs submitted another Molholt report, dated March 13,1995, before the court could rule on that motion. Id. at 5435-5520. They characterized that report as a "Medical Causation Report." It is entitled "Risk Assessments for TMI Test Cases." The stated purpose of the March 13 report was

> to examine the medical histories of each of the [Trial Plaintiffs'] cases and determine, with reasonable scientific certainty, whether or not the cancers they each developed following the 28 March 1979 TMI-2 accident are more likely than not due to radiation exposures received as a result of the accident.

Id. at 5437. A general discussion of lymphocyte depression occupies a significant portion of Molholt's Medical

Causation Report. Id. at 5442-48. His report also contains a "lymphocyte profile" for each test plaintiff. He used the profiles to determine whether the test plaintiffs' cancers were caused by ionizing radiation. Id. at 5452-99. In his Risk Assessment Report, Molholt identified six "parameters" on which he "scored" each test plaintiff on a scale of one to three; the maximum score being 18. Using these parameters and his scoring system, Molholt determined that a score of 9 or above demonstrated that causation was established with reasonable scientific certainty. Id. at 5451; 6490-94; 6572-73. Applying that methodology, Molholt concluded that the Trial Plaintiffs "received their carcinogenic insults as a result of radionuclides released by the March-April 1979 accident in the Unit 2 nuclear reactor at Three Mile Island." Id. at 5509.

When the Trial Plaintiffs filed their supplemental brief regarding Molholt's lymphocyte back-calculation dosimetry, they attached a third Molholt report, dated May 1, 1995, entitled "Utilization of Scientific Methodology in the Reconstruction of Radiation Doses to Human Receptors During the 1979 Nuclear Reactor Accident at Three Mile Island." Id. 5523-63. This report elaborates upon the April 8, 1993, Dose Exposure Report by providing supplemental lymphocyte data. In it, Molholt again concluded that "the TMI accident released radionuclides in amounts sufficient to irradiate persons in the nearby area with > 100 rems." Id. at 5523. The report also contained "an additional ten phenomena," which Molholt referred to as "corollary hypotheses." He opined that the presence of those phenomena in the TMI area confirmed his dose exposure opinion that the accident released > 100 rems [1 Sv] of ionizing radiation. Id. at 5536-27.

However, despite his three reports, the Trial Plaintiffs agreed to withdraw a portion of Molholt's proffered testimony. During the in limine hearings Trial Plaintiffs' counsel reported to the court:

> The subject of the defendants' briefing and attack on Dr. Molholt was his use of lymphocyte counts to attempt to back-calculate dose. . . . We were willing to have the [defendants' Daubert] motion granted in the limited aspect of the attack, which is the lymphocyte count, and not proffer Dr. Molholt to opine on that methodology.

App. Vol. V, at 4123. But, counsel indicated that Molholt "would still be tendered consistent with other aspects of his reports." Id. at 4124.

Not unexpectedly, a dispute arose as to what remained of Molholt's proffered testimony once the lymphocyte back-calculation methodology was withdrawn. Trial Plaintiffs claimed that they only withdrew Molholt's testimony regarding his lymphocyte methodology and its conclusions. They insisted that they had not withdrawn Molholt's proffered testimony on his "corollary hypotheses," in his May 1, 1995, report.[141] App. Vol. VII, at 6383-84. Consequently, they argued that Molholt was still able to testify about those hypotheses. The defendants disagreed and argued that Molholt characterized his corollary hypotheses "as evidence for clinical lymphocyte depression and

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141. Although not explicitly stated by the Trial Plaintiffs, their withdrawal of Molholt's lymphocyte back-calculation methodology also acted as a withdrawal of Molholt's April 8, 1993 expert report.

immunosuppression," and that this was exactly the line of testimony that Trial Plaintiffs withdrew as part of the lymphocyte back-calculation methodology. Id. at 6381.

The District Court found that the May 1, 1995 report containing the corollary hypotheses was filed in response to its February 14, 1995 order for additional briefing on the back-calculation methodology. The court reasoned that since the back-calculation methodology was withdrawn, the May 1, 1995 report "is no longer relevant to this case." Consequently, Molholt's May 1, 1995 report was also excluded, leaving only his March 13, 1995 report. 922 F.Supp. at 1026.

As noted above, Molholt's March 13, 1995 report was entitled "Risk Assessments for TMI Test Cases." In it Molholt concluded that each of the Trial Plaintiffs' cancers was caused by exposure to ionizing radiation released by the reactor accident. The District Court found Molholt's methodology scientifically unreliable and excluded Molholt's risk assessment and/or causation testimony in its entirety. Id. at 1031. The District Court also found that Molholt did not meet the reliability requirement of Rule 703. Id.

c. Discussion and Conclusions.

At the outset, the Trial Plaintiffs argue that the District Court's exclusion of Molholt's May 1, 1995, report was error because the May 1st report did not relate only to the withdrawn lymphocyte back-calculation methodology. They claim that Molholt's "corollary hypotheses" referred to in

the May 1st report constitutes a methodology, separate and apart from the lymphocyte back-calculation methodology, from which Molholt can derive a dose exposure estimate. Trial Plaintiffs' Br. at 45. We disagree.

We note, as did the District Court, see 922 F.Supp. at 1025, that the cover letter to Trial Plaintiffs' counsel accompanying Molholt's May 1st report clearly indicates that the May 1st report is in response to the District Court's February 14, 1995, order requesting supplemental information supporting the use of the lymphocyte back-calculation methodology. App. Vol. VII, at 5521. The cover letter is compelling evidence that Molholt was responding to the court's inquiries about the back-calculation methodology when he submitted the subsequent report.[142] Molholt's proffered testimony about that methodology was withdrawn by counsel. The District Court could reasonably conclude that once the methodology was withdrawn, any report submitted in support of that methodology was also withdrawn. Moreover, the text of the report clearly indicates that the corollary hypotheses do not stand as an independent methodology for determining dose estimates. Molholt's May 1st report states

> [my] first hypothesis, as stated in my affidavit of April 1993, was that if persons who were near TMI at the time of the accident can be shown to have chronic lymphocyte depression and

142. The cover letter stated: "Enclosed you will please find my response to the Court's memorandum of 14 February 1995 relating to Defendant's (sic) motion to exclude my testimony in limine in the ongoing TMI litigation."

> immunosuppression 5, 10 and 15 years later, then they must have been exposed to 100 rems during the accident.

Id. at 5524. Molholt postulated that if his first hypothesis is correct, then decreased lymphocyte levels in peripheral blood and increased cytogenetic damage in peripheral blood lymphocytes should be observed in the TMI population exposed to ionizing radiation. Id. at 5525. He opined, therefore, that the presence of both phenomena would be a confirmation of his first hypothesis. Id. Molholt then reported that others have reported both decreased lymphocyte levels and increased cytogenetic damage in TMI area residents. Id. at 5525-26. Consequently, Molholt concluded that the presence of both phenomena confirm the validity of his first hypothesis. Id.

After concluding that his first hypothesis had been confirmed, Molholt then discussed his corollary hypotheses. Id. at 5526-5531. It consisted of "ten phenomena" which he claimed should be expected following an exposure to 100 rem.[143] He claimed, again based on the reports of others,

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143. The ten phenomena the presence of which comprise Molholt's corollary hypotheses are: (1) erythema, eye irritation, nausea, vomiting and hair loss; (2) metallic and iodine tastes and smells; (3) radioiodines in excess in local fauna; (4) increased neonatal hypothyroidism from radio iodine emissions; (5) increased incidence of adult thyroid diseases; (6) increased infectious diseases in exposed persons; (7) increased infectious diseases in exposed animals; (8) increased incidence of autoimmune diseases; (9) increased incidence of cancer; and (10) radiation damage to trees. App. Vol. VII, at 5526-27.

that the ten phenomena were present and, therefore, "these additional ten hypotheses comprise a very convincing biodosimetry data set that radiation exposures exceeded doses of 100 rem during the TMI accident." Id. at 5527.

The corollary hypotheses do not stand as an independent methodology from which to arrive at a dose estimate. They were a secondary method which Molholt used as confirmation of his first hypothesis. The foundation for the first hypothesis was the lymphocyte back-calculation methodology that was withdrawn. The District Court logically concluded that if the lymphocyte back-calculation methodology was withdrawn, any evidence in support of that methodology ought to be excluded. We agree, and therefore conclude that the District Court did not abuse its discretion in excluding the May 1, 1995 report.

Consequently, only Molholt's March 13, 1995, "Risk Assessment for TMI Test Cases" report remained. That report purported to be a causation report that inquired into whether the Trial Plaintiffs' cancers were caused by ionizing radiation from the reactor accident. However, Molholt wrote that the report focused "on three aspects of the histories of each test plaintiff" rather than the "mechanisms of radiation carcinogenesis." Id. at 5437. The three "aspects" were:

> 1. Were test plaintiffs exposed to sufficient ionizing radiation in 1979 to experience lymphocyte depression and/or immunosuppression? Blood analyses and decline in health status are indicators.

> 2. Were there other indications by Plaintiffs of acute radiation exposure at the time of the TMI-2 accident, such as erythema, nausea, iodine taste, etc.?
>
> 3. Were the test plaintiffs in areas of known radiation exposure at the time of the TMI-2 accident, i.e., downwind or in areas which have borne subsequent evidence of radiation exposure such as arboreal apical ablation?

Id. Presumably in an effort to focus on these three aspects, Molholt developed six "parameters" on which he scored each plaintiff. He described the parameters as "relevant causal criteria," and stated that he "attempted to apply four weighted scores to" each of the six "parameters," to arrive at a "determination of cancer causality as resulting from TMI-2 accident emissions with reasonable scientific certainty." A score of > 50 percent established "reasonable scientific certainty for causality." Id. at 5451. The six parameters are:

> Proximity to TMI — taking into account not only the actual distance from Three Mile Island but whether or not the test plaintiff was located downwind from the TMI-2 reactor during the accident and for what period of time.
>
> Acute Symptomatology — acute signs of radiation exposure during the accident, including erythema, nausea, eye or mucous membrane irritation and metallic taste or smell (these require relatively high doses).

Appendix A

> Radiation-Damaged Trees — evidence of radiation damage in trees in the immediate area frequented by the test plaintiffs during the accident.
>
> Lymphocyte Depression and Immunosuppression — the continuing degree of lymphocyte depression following March 1979 as well as immunosuppression as indicated by increased susceptibility to infections diseases. For two test plaintiffs, cytogenetic analyses are available.
>
> Age of Test Plaintiff at Cancer Diagnosis — weighted high for youngest cases, median for 20s and 30s, low for 40s and 50s and negatively for > 60.
>
> Lag Time — weighted high for > 5 years for solid tumors, 2 years for leukemias and less as time of diagnosis approaches 1979.

Id. at 5451. Based on the score Molholt assigned to each trial plaintiff after weighing each parameter, he concluded that the Trial Plaintiffs' cancers were caused by the radionuclides released as a result of the accident. Id. at 5541; 5509.

We are at a loss to determine how Molholt scored each parameter to arrive at his causation conclusion. In his report, Molholt wrote that "[t]hese six contributors to causal certainty [i.e., the parameters] are not equally weighted." Id. But, at the in limine hearing, he testified that "in general,

and I don't mean specifically, but in general, I attempted to weigh these six criteria equally." Id. at 6571. On cross-examination, he attempted to explain the contradiction as follows:

> A: [A]lthough my objective was to weigh each of these equally, that is, to give them one-sixth of the total — actually 16.6 percent of the total score, in fact, when there was an outstanding criterion like dicentric chromosome formation, that tended to overwhelm the other five criteria, such that if I have been in a position of making the 50 percent reasonable scientific certainty standard employed or not, in other words, if I was at that boundary, I would have weighed the chromosomal criteria more than damaged trees or more than lymphocyte depression or more than lag time.
>
> Q: So if you got a positive answer on chromosome abnormalities, that carried the day?
>
> A: If I were at that boundary between certainty and uncertainty, which is the 50 percent standard that has been employed, at least up until Daubert and Paoli [II], what I was attempting to do was to quantify these criteria in such a way that I could, on an individual basis of each one of these, make a 50 percent determination, but then collectively to say, on that system of three, two, one, you have six criteria, the highest score is 18 if all six criteria are satisfied in terms of what we know about

> exposure requirements and carcinogenesis, radiation carcinogenesis.
>
> So if those six criteria were all satisfied to the fullest, you would have a score of 18. That's the highest you could get. The lowest you could get is, if none of them were satisfied at all, and that's zero. So I took nine as being the boundary.
>
> Q: And if they hit nine, then you said that's enough?
>
> A: No, I didn't. That's when I would reach into my basket of tricks and pull out dicentric chromosomes or some other characteristic that I thought deserved more credence than trying to equally weigh them. Now, as it turned out . . . I didn't have any that were nine. . . . They were all ten or more.

Id. at 6572-73. From this exchange, we can only conclude that the methodology Molholt used to score and weigh his parameters to determine causation is purely subjective.[144] In

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144. Because Molholt's parameter scoring methodology is entirely subjective it is obvious that it does not satisfy a number of the Daubert factors. It was never peer reviewed, there is no known or potential rate of error, there are no discernable standards governing its operation, and it is not generally accepted. Daubert, at 593-594, 113 S.Ct. 2786. Further, and significantly, it is impossible to test a hypothesis generated by a subjective methodology because the only person capable of testing or falsifying the hypothesis is the creator of the methodology.

order for expert testimony to meet Daubert's reliability standard, it must be based on the methods and procedures of science, not on subjective belief and unsupported speculation. Kannankeril, at 805. Molholt's subjective methodology is suspect. As quoted above, he testified that when he was at the boundary between certainty and uncertainty, i.e., when according to his own scoring system a trial plaintiff's score reached nine, he "would reach into [his] basket of tricks" to pull out something which he thought deserved more weight. Not unexpectedly, he always found something in his magical basket which caused the score to exceed nine and pass from uncertainty to certainty. However, we are as unimpressed with his "Felixian"[145] basket of tricks as the District Court was, and we conclude that the exclusion of Molholt's March 13, 1995 report was not an abuse of discretion.

viii. Sigmund Zakrzewski.

a. Qualifications.

Sigmund Zakrzewski earned a Ph.D. in biochemistry from the University of Hamburg in Germany and has spent his entire career in cancer research. For most of his professional life, he was the Principal Cancer Research Scientist at the Roswell Park Cancer Institute in Buffalo, New York. He is presently a Professor Emeritus at the State University of New York — Buffalo, an appointment he had held since 1987. App. Vol. IX, at 7912-7914. He was offered

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145. See Felix The Cat: "Whenever he gets in a fix, he reaches into his bag of tricks." Chris Milburn, Felix, Felix, Felix (visited Sept. 13, 1999) <http://www.primenet.com/cmilburn/felix/felix.htm>.

as an expert to give his opinion as to the cause of the cancers of the Trial Plaintiffs.[146]

b. Zakrzewski's Opinion.

Zakrzewski's report, dated September 15, 1994, Id. at 7920-31, states that in 1993 he was contacted by Trial Plaintiffs' counsel and asked "to review cases of different types of cancer . . . allegedly due to the release of radioactivity resulting from the nuclear accident . . ." at TMI-2. Id. at 7920. As a result, he reviewed "ten cases involving two cases of chronic leukemia, two cases of acute leukemia, two cases of thyroid cancer, one case of thyroid adenoma (benign tumor), one case of osteogenic sarcoma, one case of breast cancer and one case of adenosarcoma of ovaries." Id. at 7921.[147] His report details nine factors he considered in evaluating the cases, viz., (1) the type of cancer; (2) age of victims at the time of the accident; (3) occupation at the time of the accident; (4) whereabouts of the victims at the time of the accident; (5) latency period between alleged exposure and diagnosis; (6) other cancer cases in the

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146. Zakrzewski is not a medical doctor, toxicologist or risk assessor. Consequently, his qualifications to give an opinion on causation were attacked by the defendants. The defendants also attacked his qualifications on the grounds that none of his cancer research involved the health effects of ionizing radiation. However, the District Court found that he met "the threshold requirement for qualification as an expert." 922 F.Supp. 1038, 1049 (M.D.Pa.1996). That finding is not attacked on appeal.

147. In other words, Zakrzewski reviewed the Trial Plaintiffs' cases.

neighborhood of the plaintiff's residence or the place of business; (7) possible exposure to carcinogens other than radiation; (8) prior exposure to medical radiation; and (9) any evidence, other than the victim's disease indicating the possibility of exposure to ionizing radiation. Id. He explained that because he is not a physician he did not attempt to review any medical records. Rather, he relied on the diagnosis of the physician of each trial plaintiff's case he evaluated. Id. He concluded that "the four cases of leukemia . . . were most likely caused by exposure to radiation released during the TMI accident," Id. at 7923, that "the three cases of thyroid cancer were most likely caused by radioactive fallout resulting from the TMI accident," Id. at 7924, that "the most likely cause of [the] osteosarcoma is exposure to radioactive fallout originating from the nuclear accident at TMI," and that "whole body exposure to radiation is the most likely cause of the breast cancer and the ovarian cancer." Id. at 7926.

The District Court sustained defendants' Daubert challenge to Zakrzewski's testimony. See In re TMI Litigation Cases Consolidated II, 922 F.Supp. 1038, 1051 (M.D.Pa.1996).

c. Discussion and Conclusions.

At the in limine hearing, Zakrzewski testified that the only data he relied upon in arriving at his causation opinion were a summary sheet for each trial plaintiff. App. Vol. IX, at 8158. Each summary sheet contained a family history of other diseases, as well as

> personal information about the person, age at the time of accident, age at the time of diagnosis, location of the residence and location of place of work, and of course, occupation, or school, and any possible other factors which could have caused the malignancy. And also, some information about personal observation, were you aware of the accident, did you observe any vegetation damage, and similar information.

Id. at 8136. The summary sheets were prepared by Trial Plaintiffs' counsel and transmitted to him by a woman identified as a consultant to the plaintiffs.[148] Id. at 8157-58. Zakrzewski testified that he did not develop a methodology for assessing causation and then request appropriate data. App. Vol. IX, at 8158. Rather, it appears that he was provided with the data and then constructed a methodology. Id. at 8158-8159.

Earlier, we noted the interaction between Rule 702 and Rule 703. The latter requires that the trial judge determine whether the proffered expert "is basing his or her opinion on a type of data reasonably relied upon by experts." Paoli II, at 748. Here, we cannot fault Zakrzewski for relying on the diagnoses of the Trial Plaintiffs' physicians. He did so because of his realization of the limitations endemic to his lack of medical training and expertise. However, we share

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148. That woman was Marjorie Aamodt, who, along with her husband Norman, "have been identified as 'consultants' to Plaintiffs in the context of this litigation." 922 F.Supp. at 1047. The District Court noted that the Aamodt's are "not listed as expert witnesses and have not supplied any expert reports for this case." Id.

the District Court's concern over reliance on the summary sheets prepared by Trial Plaintiffs' counsel, and given to him by plaintiffs' consultant. As the District Court noted: "No evidence has been placed on the record as to how these summary sheets were created." 922 F.Supp. at 1050. They have no demonstrated indicia of reliability, and it is the burden of the party offering the expert scientific testimony to demonstrate reliability by a preponderance of the evidence. Paoli II, at 744. Absent some evidence as to how the sheets were prepared and the sources of the information contained in them, it is impossible to assess their reliability.

The Trial Plaintiffs do not waste any ink trying to convince us that the summary sheets furnish adequate support for an expert opinion. Consequently, our analysis of this issue could end here, and we could merely affirm the exclusion of Zakrzewski's testimony with no further discussion. However, Trial Plaintiffs claim that Zakrzewski did not rely solely on the summary sheets. They assert that he also relied on the "scientific evidence" of plaintiffs other experts in arriving at his causation opinion. Trial Plaintiffs Br. at 56. For example, Zakrzewski assumed that the Trial Plaintiffs were exposed to radiation and the basis for that assumption was the dose evidence developed by others, i.e., damaged trees (Shevchenko and Gunckel), impaired immunity (Tarasenko and Molholt); and anecdotal accounts of radiation-induced illnesses (Gunckel). App. Vol. IX, at 7927-7929. Essentially, the Trial Plaintiffs attempt to show reasonable reliance by postulating that their other experts' opinions were sufficiently reliable to support Zakrzewski's expert opinion. However, the reliability of those other opinions is the focus of our entire inquiry. Trial Plaintiffs' argument in this regard is the

intellectual equivalent of having the left hand put the rabbit into the hat so it can be pulled out by the right hand. We have already upheld the District Court's exclusion of the evidence Trial Plaintiffs now seek to morph into a reliable foundation for Zakrzewski's opinion. We conclude that the District Court did not abuse its discretion by excluding Zakrzewski's testimony.

ix. Theodor Sterling.

a. Qualifications.

Theodor Sterling earned a Ph.D. from the Tulane University. He is an epidemiologist and a Professor on the Faculty of Applied Science and School of Computing Science at Simon Fraser University in Burnaby, British Columbia. Sterling notes that, generally, his research is "directed toward the understanding of the effects of environment on human health." App. Vol. IX, at 8190. More particularly, he reports that his "major areas of research have been the effects of air pollutants including tobacco; the effects of herbicides especially of mixtures of herbicides known as Agent Orange; the effects of radiation both for treatment of, and source of, cancer, the effects of occupational exposures especially to asbestos, dioxins in various forms and formaldehyde." Id.

Sterling submitted a report, dated April 25, 1995, entitled "Analysis of the Elevated Cancer Risks Associated with the 1979 Three Mile Accident."[149] Id. at 8222-8243. In it, he

149. Sterling submitted a second report in the form of a "Supplemental Affidavit" dated February 2, 1996. Id. at 8244-51. (Cont'd)

wrote that the "scientific hypothesis investigated is whether the health of individuals living near Three Mile Island was adversely affected by the accidental release of radioactivity." Id. at 8237.

b. Sterling's Opinion.

At the in limine hearing, Sterling testified that he was retained to perform an epidemiological analysis on certain data from certain groups of people who lived in the Three Mile Island area. App. Vol. IX, at 8282. His report identified those groups[150] and reported the results of his analysis:

> The Haystack Garment Workers: A cohort[151] of 69 women employed by Hesteco Manufacturing

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(Cont'd)
However, the District Court found that Sterling's February 2, 1996 Supplemental Affidavit was untimely filed and excluded it. In re TMI Litigation Cases Consolidated II, 922 F.Supp. 1038, 1046 (M.D.Pa.1996).

150. In addition to the groups listed, Sterling's report contained an analysis of a group of 15 female high-school aged softball players. App.Vol. IX, at 8225. However, this group was withdrawn from Sterling's proffered testimony. 922 F.Supp. at 1047.

151. In epidemiology, a cohort is "[a]ny designated group of persons followed or traced over a period of time to examine health or mortality experience." FEDERAL JUDICIAL CENTER, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 172 (1994). In a cohort study, the epidemiologist

> identifies two groups of individuals: (1) individuals who have been exposed to a substance that is thought might

(Cont'd)

Co. and present at the factory premises at the time of the accident. Ten women have developed cancer since then. This number of cancers is greater than would be expected had the cohort developed cancer at the same incidence rate as a comparable group of women selected from the general population.

The Harrisburg Schoolchildren: A cohort consisting of 1991 students attending four

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(Cont'd)

> cause a disease and (2) individuals who have not been exposed. Both groups are followed for a specified length of time, and the proportion of each group that develops the disease is compared. If the exposure is associated with or causes the disease, the [epidemiologist] would expect a greater proportion of the exposed individuals to develop the disease.

Id. at 134. Cohort studies are also known as concurrent studies, follow-up studies, incidence studies, longitudinal studies and prospective studies and these alternative names "describe an essential feature of the method, which is observation of the population for a sufficient number of person-years to generate reliable incidence or mortality rates in the population subsets." This generally implies study of a large population, study for a prolonged period (years), or both. Id. at 173. Cohort studies can also be retrospective. In a retrospective cohort study, the epidemiologist gathers historical data about exposure and disease outcome of the exposed cohort. Id. at 134 n. 35. The health effects are identified and the date analyzed in a manner similar to that used in a prospective study. "The observed health effects are then compared with health effects expected based on an appropriate control population or related to variations in estimated doses." RADIATION DOSE RECONSTRUCTION, at 69.

Appendix A

Harrisburg elementary schools at the time of the accident. At least six of these students have developed cancer. This number of cancers is greater than would be expected had the cohort developed cancer at the same incidence rate as a comparable group of children selected from the general population.

The Ten Mile Cohort: A cohort consisting of all persons under the age of 25 years at the time of the accident, living within a ten mile radius of Three Mile Island. This cohort showed a dramatic increase in leukemia incidence rates following the accident.

First Trimester Infants: The cohort of infants born to mothers who were in the first trimester of pregnancy at the time of the accident, and who lived within a 10 mile radius of Three Mile Island. This cohort showed a greater incidence of congenital malformations than a cohort of infants to mothers from the same region who became pregnant after the accident, and than a cohort of infants born in Atlanta from 1968 to 1979.

Id. at 8225-26. Sterling answered his hypothesis in the affirmative. The District Court excluded Sterling's testimony as scientifically unreliable under Rule 702. 922 F.Supp. at 1048. The court also excluded it under Rule 703, because the court concluded that Sterling relied upon data that experts in the field would find unreliable. Id.

c. Discussion and Conclusions.

Sterling admits that "[s]tatistical analysis of epidemiological data is much abused." App. Vol. IX, at 8237. Nonetheless, there are methods by which the epidemiologist can design a study to minimize, if not entirely eliminate, bias and error.[152] The REFERENCE MANUAL ON SCIENTIFIC EVIDENCE notes that, although epidemiological findings always involve a degree of uncertainty,

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152. Epidemiologists define "bias" in a way that differs from its ordinary meaning. They define it as:

> [a]ny effect at any stage of investigation or inference tending to produce results that depart systematically from the true values. The term "bias" does not necessarily carry an imputation of prejudice or other subjective factor, such as the experimenter's desire for a particular outcome. This differs from conventional usage in which bias refers to a partisan point of view.
>
> * * *
>
> The two main types of bias are selection bias, in which there is a systematic difference between those individuals included in the study and those who are not, and information bias, which involves error in measuring disease or exposure among those included in the study.

REFERENCE MANUAL ON SCIENTIFIC EVIDENCE, at 172. Error, also called random error or sampling error, "is that due to chance when the result obtained in the sample differs from the result that would be obtained if the entire population (universe) were studied." Id. at 174.

> systematic methods for assessing the characteristics of persons included in the study and their risk of disease can be used to help rule out known sources of bias and error. . . . The epidemiologist uses sample size calculations and inclusion and exclusion criteria for identifying exposed and unexposed groups . . . to reduce potential bias and error.

REFERENCE MANUAL ON SCIENTIFIC EVIDENCE, at 127. In determining who will comprise the study group, the epidemiologist must articulate "[a] list of criteria for inclusion in and exclusion from the study." Id. at 138. These criteria should be documented clearly before the subjects are recruited for the study to ensure that "no overt or covert biases enter into the selection process." Id. The danger inherent in not clearly articulating criteria for inclusion and exclusion is that any biases that enter into the selection process "could lead to erroneous inferences regarding causation." Id.

Here, Sterling had absolutely no part in the selection of the participants he studied. During cross-examination at the in limine hearing, he testified that the participants in the study groups and the data given to him was selected by the Aamodts:

> Q: How did you go about looking for the groups that you analyzed here?
>
> A: We were contacted by Mrs. Aamodt and Mr. Aamodt who had done some additional — had

> some done work (sic), and we were asked to calculate risks for these groups.
>
> Q: So they selected the groups and provided you with the data, and then you did the statistical calculations regarding the data they provided?
>
> A: That is correct.

App. Vol. IX, at 8284. As noted above, the Aamodts also provided data to Zakrzewksi for his report. Apparently, they are the eminences grises of this litigation. However, despite the central role the Aamodts seem to have played in the research conducted by various experts proffered by Trial Plaintiffs, the Trial Plaintiffs failed to demonstrate that the Aamodts were qualified to select the participants for Sterling's study. See 922 F.Supp. at 1048 ("[T]here is no evidence on the record from which the court can make any judgment regarding the qualifications of the Aamodts to create and execute the selection portion of an epidemiological study design."). The Trial Plaintiffs have not referred us to anything in the record from which we could determine that the Aamodts are qualified to select the participants and the data for a cohort study. Consequently, the data upon which Sterling relied are woefully lacking in Rule 703 reliability.

The absence of evidence that the Aamodts selected the participants in the groups in a manner consistent with that suggested by the Reference Manual on Scientific Evidence creates a profound flaw in Sterling's methodology. There is no way to insure that participants were not selected or excluded in a manner that would bias the study. Moreover,

it appears that there are no articulated selection criteria here because the Aamodts selected participants whom they knew had cancer. The Aamodts included certain of the Trial Plaintiffs in the selected groups. App. Vol. IX, at 8248-50. The groups Sterling studied therefore had a built-in bias so that a finding of increased cancer incidence was inevitable. An epidemiological opinion based on such a study is not reliable, and the District Court did not abuse its discretion when it excluded Sterling's testimony.

x. Steven Wing.

a. Qualifications.

Steven Wing earned a Ph.D. in epidemiology from the University of North Carolina in 1983 and is currently an Assistant Professor in the Department of Epidemiology at the University of North Carolina at Chapel Hill.[153] He submitted two reports. The first, dated January of 1994, is entitled, "Mortality Trends in Relation to the Accident at Three Mile Island." App. Vol. VIII, at 6828-6840. Trial Plaintiffs refer to this report as the "Mortality Study." The second report, dated February 25, 1995, is entitled "Re-Analysis of Cancer Incidence Near Three Mile Island Nuclear Plant." Id. at 6869-82. Wing's second report is a re-analysis of the data collected in connection with a cancer incidence study in the TMI area conducted by Maureen C. Hatch, an epidemiologist from Columbia University, and others. See Maureen C. Hatch, Jan Beyea, Jeri W. Nieves and Mervyn Susser, Cancer Near the Three Mile Island

153. Wing's qualifications as an expert were not challenged.

Nuclear Plant: Radiation Emissions, 132 Am. J. of Epidemiology 397 (1990) (hereinafter "Hatch/Susser study"). The Trial Plaintiffs refer to Wing's February 25th report as the "Cancer Incidence Study."

Each report is discussed separately.

b. Wing's Mortality Study.

In his Mortality Study, Wing wrote that Norman Aamodt, the plaintiffs' consultant, contacted him and asked him to review the results of a study of mortality trends which Aamodt had conducted. App. Vol. VIII, at 6831. According to Aamodt's study,[154] mortality trends in the five counties surrounding Three Mile Island were higher in 1980 "than would have been expected based on the trends for earlier and later years." Id. Aamodt suggested to Wing that "high

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154. There is nothing in the record that indicates that Aamodt is qualified to perform an epidemiological study. Aamodt's study was, however, very elementary. Wing described it as follows:

> Aamodt conducted his epidemiological analysis using paper and pencil and the vital statistics data published by the Pennsylvania Department of Health. He added the annual numbers of death for the five counties around TMI (Cumberland, Dauphin, Lebanon, Lancaster and York) and divided each number by the total estimated population, provided by the State or computed by extrapolation, to form annual crude death rates. When he plotted the rates over time, he noted an abrupt rise in the death rate in 1980, the year after the accident.

App. Vol. VIII, at 6832.

doses of radiation to small populations residing on the elevated terrain in the path of the noble gas plumes from the TMI accident lead to the deaths of some older people who were already in poor health. . . ." Id. Wing confirmed the results of Aamodt's mortality study and agreed to conduct a more sophisticated study of mortality rates in the Three Mile Island Area. Id. at 6832.

In that follow up analysis, Wing had access to computerized records of death and population counts by age in the five-county area. He calculated age-adjusted death rates and isolated for specific causes of death. Id. at 6833. His analysis also included a study of mortality trends in all Pennsylvania counties and in the continental United States. Id. at 6834; 6836. Wing concluded that the following major findings suggested an effect of the TMI accident:

> 1. an elevation of 1980 mortality in the five counties around TMI amounting to about 490 more deaths than would have been expected from 1979 rates;
>
> 2. an increase in cancer mortality among young children in the five counties in 1980-82;
>
> 3. an increase of infectious disease death rates in the five counties after the accident; and
>
> 4. a geographic clustering of areas with higher-than-expected 1980 mortality in parts of Pennsylvania and the Middle Atlantic and New England States. These results, considered in the

> context of other studies and uncertainties about exposure estimates, may reflect mortality impacts of high-level radiation exposures from the 1979 accident at Three Mile Island.

Id. at 6839.

The District Court sustained the defendants' Rule 702 challenge to Wings' mortality study testimony and excluded it following an in limine hearing. The court held that the study doesn't "fit" as required by Rule 702.[155] In re TMI Litigation Cases Consolidated II, 911 F.Supp. 775, 820 (M.D.Pa.1996).

c. Discussion and Conclusions.

We agree that Wing's mortality testimony lacks the requisite fit under Rule 702.[156] Wing wrote that the "ability of an epidemiological analysis to detect health effects of an environmental agent depends on having good information

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155. The District Court did find, however, that Wing's mortality study met the reliability test of Daubert/Paoli II, 911 F.Supp. at 819.

156. The District Court also found that Wing's testimony would "unnecessarily confuse the jury," and was therefore inadmissible under Fed.R.Evid. 403. Rule 403 provides: "Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." However, because we find that Wing's mortality testimony does not "fit," we need not review the District Court's Rule 403 analysis.

on exposures of individuals and the relevant biological responses." App. Vol. VIII, at 6838. However, he conceded that he had no information on dose exposure, and cautioned that the results of his study "should be interpreted in that context." Id. He seconded his own caveat at the in limine hearing when he conceded that few specific conclusions could be drawn between the increased mortality his study found and the releases from the reactor accident because he did not have any estimates of radiation doses. On direct examination, he testified:

> Well, it's important to note that this study does not have any estimates of radiation doses, and it's a study simply of death rates, and as such, there are not very specific conclusions that can be drawn. . . . So it's not an analysis of the association between dose and mortality. It's an investigation of an observation that was originally made in Vital Statistics data to understand who experienced this in terms of the age groups, what causes of death in the local area showed this, and which did not.

Id. at 7214-15. On cross-examination, he admitted that even though his study demonstrated an elevated mortality in 1980, he could not attribute that elevation to radiation.[157] In fact, Wing conceded that the mortality elevation was probably influenced by other factors. On cross-examination, the following exchange occurred:

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157. He testified: "I can't conclude that the elevation, the observed elevation, is due to radiation, from this study." Id. at 7250.

> Q: Am I correct to understand, then, that the mortality data you present may also reflect other factors?
>
> A: I'm quite sure other factors are reflected, yes. And I mean to say by that, other factors, other additional factors.[158]

Id. at 7250.

Wing's admission that his study was a mortality study only, and not an analysis of an association[159] between dose and mortality, combined with his admission that he was unable to conclude that the elevated mortality was due to radiation exposure clearly demonstrates a lack of "fit." He

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158. In his report, Wing wrote that one factor explaining, or tending to explain, the increased mortality he observed in 1980 may be the epidemics of pneumonia and influenza that occurred in the winters of 1979-80 and 1980-81. App. Vol. VIII, at 6839. However, at the in limine hearing, Wing testified that he investigated the pattern of flu epidemics, but "did not see any clear evidence that this was the year with the big flu epidemic, and therefore, that's why mortality was elevated in that year." Id. at 7251. Nonetheless, Wing held to his opinion that the increased mortality may also reflect other factors.

159. Association is a term of art in epidemiology. It is defined as "[t]he degree of statistical dependence between two or more events or variables. Events are said to be associated when they occur more or less frequently together than one would expect by chance. Association does not necessarily imply a causal relationship. Events are said not to have an association when the agent (or independent variable) has no apparent effect on the incidence of a disease (the dependent variable)." REFERENCE MANUAL ON SCIENTIFIC EVIDENCE, at 171.

does not even make a tenuous connection between the radionuclides released during the reactor accident and the elevated cancer mortality his study revealed. Consequently, the District Court did not abuse its discretion in excluding Wing's mortality testimony.[160]

d. Wing's Cancer Incidence Study.

As noted above, Wing's cancer incidence study is a re-analysis of the data in the Hatch/Susser study. The Hatch/Susser study was undertaken at the request of the Three Mile Island Public Health Fund[161] and tested "a prior hypotheses that risks of specified cancers may have been raised by exposure to radiation emanating" from TMI-2 as a result of the reactor accident. Hatch/Susser study, at 398. There were 5,493 incident cases of cancer diagnosed in study area residents from January 1, 1975, to December 31, 1985. Id. at 399-400. Hatch, Susser et al., divided the TMI area into geographical study tracts and analyzed pre and post-accident cancer incidence relative to dose, both from accident emissions and from routine plant emissions, within those tracts.[162] Id. at 400-02. The dose exposure level used for

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160. The District Court viewed Wing's mortality study as a "preliminary analysis, meant to be supplemented by further study and testing." 911 F.Supp. at 820. We agree with that view. Wing's mortality study strikes us as more of a work-in-progress than a final epidemiological study.

161. See p. 661 n. 83, supra.

162. The Hatch/Susser study dose estimates were derived from original plant data, meteorological data from a weather station maintained at the TMI plant, and a Gaussian plume dispersion model. Hatch/Susser study, at 400-01.

accident emissions was very low — an average of approximately 0.1 Sv, with 1 mSv the projected maximal dose. Id. at 400. Routine plant emissions were estimated to be 0.006 mSv per year. Id.

The primary cancers Hatch/Susser, et al., considered were leukemia[163] and childhood cancers.[164] However, the grouping of " 'all cancers' was selected for the sake of completeness." Id. at 400. The Hatch/Susser study concluded:

> For accident emissions, the authors failed to find definite effects of exposure on the cancer types and population subgroups thought to be most susceptible to radiation. No associations were seen for leukemia in adults or for childhood cancers as a group. For leukemia in children, the odds ratio was raised, but cases were few (n = 4), and the estimate was highly variable. Moreover, rates of childhood leukemia in the Three Mile Island area are low compared with national and regional rates. For exposure to routine emissions, the odds ratios were raised for childhood cancers as a whole and for childhood leukemia, but confidence intervals[165] were wide and included

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163. Hatch/Susser excluded chronic lymphocytic leukemia, which is considered to be nonradiogenic. Hatch/Susser study, at 400.

164. Leukemia and childhood malignancies were selected because of "either short latency periods or sensitivity to low-dose radiation, or both." Hatch/Susser study, at 400.

165. A confidence interval is "[a] range of values within which the results of a study sample would be likely to fall if the study

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Appendix A

1.0. For leukemia in adults, there was a negative trend. Trends for two types of cancer ran counter to expectation. Non-Hodgkin's lymphoma showed raised risks relative to both accident and routine emissions; lung cancer (adjusted only indirectly for smoking) showed raised risks relative to accident emissions, routine emissions and background gamma radiation. Overall, the pattern of results does not provide convincing evidence that radiation releases from the Three Mile Island nuclear facility influenced cancer risk during the limited period of follow-up.

Id. at 397.

Wing's reanalysis of the Hatch/Susser data began with the a priori hypothesis that the levels of radiation exposures were higher than the levels used in the Hatch/Susser study. App. Vol. VIII, at 6871. That hypothesis was based on the "ongoing collection of evidence suggestive of high-level radiation exposures in the pathways of radioactive gas plumes." Id. Using that hypothesis, Wing reanalyzed the Hatch/Susser data based on the relationship between cancer incidence and accident exposures characterized by a single

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were repeated numerous times. . . . The width of the confidence interval provides an indication of the precision of the point estimate or relative risk found in the study; the narrower the confidence interval, the greater the confidence in the relative risk estimate found in the study. Where the confidence interval contains a relative risk of 1.0, the results of the study are not statistically significant." REFERENCE MANUAL ON SCIENTIFIC EVIDENCE, at 173.

dose response line derived from the cancer incidence in all of the study tracts. He focused on "incidence of all cancers and lung cancer" and the category of "all leukemias." Id. at 6875. The dose response line has a rising slope when increased dose corresponds to an increase of cancer, a zero slope when there is no change in cancer incidence with increased dose, or a negative slope when there is a decline in cancer incidence corresponding to an increase in dose. Id. at 6874; 7232-32. Wing determined the difference between the dose response lines in the pre-accident period (1976-79) and the post-accident period (1981-1985). Id. at 7231. Statistical analysis was then used to derive the slope of the dose response line which best fits the cancer incidence data across all study tracts.

Wing's re-analysis showed "that cancer rates, and specifically lung cancer and leukemia, increased more following the accident in areas estimated to have been in the pathway of radioactive plumes than in other areas." Id. at 6879. Consequently, he concluded that the increases in cancer incidence "are consistent with allegations that the magnitude of radiation exposures from the accident were much higher than has been assumed in past studies." Id.

The District Court found that Wing's re-analysis was "only marginally scientifically reliable." In re TMI Litigation Cases Consolidated II, 922 F.Supp. 997, 1019 (M.D.Pa.1996). However, because "marginally scientifically reliable is not unreliable," the court found that the re-analysis met the Daubert/Paoli II reliability standards. Id. Consequently, the cancer incidence study was ruled admissible, except for that portion of the study which

analyzed lung cancer. 911 F.Supp. at 823. The District Court believed that the lung cancer portion of the cancer incidence study did not meet Rule 702's fit requirement because of the latency period for lung cancer which Wing used in his study. Id. at 822-23.

e. Discussion and Conclusions

The District Court's exclusion of the lung cancer portion of Wing's cancer incidence study is troublesome. Wing's re-analysis demonstrated that cancer rates, and specifically lung cancer and leukemia rates, increased following the accident in those areas estimated to have been in the path of the alleged radioactive plume. He used a minimum latency period for lung cancer of four to eight years, and he based that period upon a study of lung cancer in uranium miners.[166] However, the defendants' expert[167] testified that the general latency period for solid tumors, other than thyroid cancer, but including lung cancer, is between ten and fifteen years. App. Vol. XIV, at 11959. In addition, the defendants claim that Wing misread the study from which he derived his lung

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166. The study is JAY H. LUBIN, ET AL., RADON AND LUNG CANCER RISK: A JOINT ANALYSIS OF 11 UNDERGROUND MINERS STUDIES (U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, NIH Publication No. 94-3644, 1994), and is found at App. Vol. VIII, at 7294-7310.

167. The defendants' expert who testified as to the latency period for lung cancer was David G. Hoel. Hoel is the Professor and Chair of the Department of Biometry and Epidemiology of the Medical University of South Carolina in Charleston, South Carolina. App. Vol. XII, at 10352.

cancer latency period. In their view, a correct reading of that study would demonstrate that the latency period for lung cancer is up to sixteen years. Appellees' Br. at 52.

The issue of the latency period for lung cancer is important because of the time frame of Wing's cancer incidence study. The Hatch/Susser study used incident cancers from 1975 to 1985, and Wing used the same incident cancers. The reactor accident occurred in 1979 and the last year covered by his study was 1985. Therefore, the period between the accident and the last year of the study was six years. Consequently, the ability to make a plausible association between the accident and a diagnosis of post-accident lung cancer depends upon the length of the latency period. If the latency period is four to eight years, as Wing claimed, then a sufficient latency period elapsed between exposure and diagnosis to make a plausible association between the exposure and the lung cancer. If, however, the latency period is ten to fifteen years, as the defendants claim, then an insufficient latency period elapsed between the date of the accident and the last year of the study to draw a plausible association between radiation released by the reactor accident and a diagnosis of lung cancer.

The District Court decided to exclude the lung cancer portion of Wing's cancer incidence study because it lacked "fit." 911 F.Supp. at 823. It found that Wing's findings regarding all cancers and leukemia suggest increased levels of radiation exposure, and therefore, "fit," because they are relevant to a fact in issue, viz., the radiation dose received by the plaintiffs. Id. at 823. However, the court held that "failure to explain the discrepancy between expected latency

periods and his lung cancer findings" negates his study's fitness. Id.

We assume that the District Court believed that Wing used an insufficient latency period between the date of the accident and diagnoses of post-accident lung cancer and therefore could not make an association between exposure and onset of lung cancer. However, that finding assumes that the latency period was ten to fifteen years as claimed by defendants. Thus, it appears that the District Court credited the defendants' expert over Wing. We believe that was error.

Earlier in its analysis of Wing's cancer incidence study, the District Court wrote that the lung cancer latency question "decreases the credibility of Dr. Wing's findings." Id. at 822. However, such credibility issues arise only after admissibility has been determined, Kannankeril, at 806, and they are decided by the jury. See Breidor v. Sears, Roebuck & Co., 722 F.2d 1134, 1138-39 (3d Cir.1983) ("Where there is a logical basis for an expert's opinion testimony, the credibility and weight of that testimony is to be determined by the jury, not the trial judge."). Here, by crediting the opinion of the defendants' expert, the District Court conflated its gatekeeping function with the fact-finders' function as the assessor of credibility. See Kannankeril, at 809 ("The trial judge must be careful not to mistake credibility questions for admissibility questions.").

Consequently, we believe that it was error for the District Court to exclude Wing's lung cancer testimony.

xi. Douglas Crawford-Brown.

a. Qualifications.

Douglas Crawford-Brown earned a Ph.D. in nuclear science and health physics from the Georgia Institute of Technology. He is currently a Professor at the University of North Carolina at Chapel Hill, North Carolina, and the Director of the Institute for Environmental Studies at the University. He is also a member of the faculty of the Ecology Program, and the faculty of the Public Policy Analysis Program.[168] App. Vol. V, at 3198. He was offered as an expert in exposure assessment, which he said is a "distinct stage[ ] of risk assessment." Id. at 3200. He defined "risk assessment" as a

> process by which you first determine whether a substance or a risk agent is able to produce effects, and then you determine the amount of exposure or the amount of the substance that's in the environment, and then you determine the relationship between exposure and severity of effects. And then you summarize that as an estimate of the probability and severity of effects and uncertainty distribution in a distribution of variability in the population.

Id. at 3199.

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168. Crawford-Brown's qualifications were not in dispute.

b. Crawford-Brown's Opinion.

The Trial Plaintiffs characterized Crawford-Brown "as a kind of chairperson" for their "team of experts," Trial Plaintiffs' Br. at 16. He reviewed the reports of the Trial Plaintiffs' other dose exposure experts and, on the basis of that review, offered an opinion as to the radiation dose to which Three Mile Island area residents were exposed as a result of the reactor accident. In his February 27, 1995, Affidavit, he opined as follows:

> Based on the . . . considerations of evidence, and conditional on establishing that the effects noted were in most likelihood caused by radiation exposures, it is my professional opinion that the findings above are consistent with the claim that individuals located in the vicinity of the points of biological dosimetry received dose equivalents at levels in excess of 100 rem. This opinion in based on a full consideration of the coherence of the evidence, with similar conclusions being reached across the various inference options.

App. Vol. V, at 3081. Thus, in order to give his exposure assessment, Crawford-Brown assumed that the effects that the other dose experts claimed (chromosome dicentrics, tree damage, anecdotal reports of erythema, metallic taste, etc., increased rates of cancer post-accident) were actually caused by radiation, and he assumed that those experts' estimates of the dose required to produce those effects were correct.

The District Court excluded his proffered testimony in its entirety because it did not meet Rule 702's reliability

requirement.[169] In re TMI Litigation Cases Consolidated II, 911 F.Supp. 775, 826 (M.D.Pa.1996). The court found that Crawford-Brown's testimony was unreliable because "he chose to rely blindly upon the conclusions generated by Plaintiffs other experts," rather than evaluating the "relative strength or weakness of each of the strands of evidence (e.g., biological dosimetry data) available to him." Id. at 825.

c. Discussion and Conclusions.

We share the District Court's concern with the reliability of Crawford-Brown's "process or technique." He testified that in arriving at his conclusions he relied on the opinions of plaintiffs' other dose experts and assumed the correctness of each expert's proposition. App. Vol. V, at 3257. For example, he did not testify that the tree damage observed by Shevchenko and Gunckel was an effect of radiation. Rather, he testified that he had "to leave that to someone else who is an expert in that area to decide." Id. at 3237. Similarly, he testified that he accepted Snigiryova's dicentric enumeration for the population she studied in arriving at his dose estimate. Id. at 3212. He did not testify that increased cancer and leukemia rates observed by Wing in his cancer incidence study were caused by radiation. Rather, Crawford-Brown testified "Well, again, my opinion is conditional on another

169. The district court also found that it was inadmissible because it was irrelevant under Rule 402. 911 F.Supp. at 826. Federal Rule of Evidence 402 provides: "All relevant evidence is admissible, except as otherwise provided by the Constitution of the United States, by Act of Congress, by these rules, or by other rules prescribed by the Supreme Court pursuant to statutory authority. Evidence which is not relevant is not admissible."

expert establishing that the leukemia rates are due to radiation exposures." Id. at 3215. Thus, his opinion is somewhat analogous to the last domino in the line that begins to fall when the first domino is toppled.

Crawford-Brown admitted that (unlike Kozubov) he did not use trees for dosimetry. He testified: "If you mean has it actually been used in dosimetry studies by people like myself who do dosimetry, then no." Id. at 3235. He also testified that he had never heard of a study where cancer or leukemia rates were used to estimate dose. "I know of no cases where that's been done. I can't imagine why somebody would have done it. . . ." Id. at 3251. Moreover, he testified in his deposition that he never made any attempt to assess the validity of any of the assumptions the other experts used to formulate their opinions.

> Q: With respect to any of the stated assumptions, do you make any effort to assess their validity?
>
> A: No. They are hypothetical in each case.
>
> Q: This is maybe asking the same question or a closely related question. But have you made any effort to assess the probability that these assumptions are true or not?
>
> A: No.

Id. at 3157.

However, by not assessing the validity of the other experts' assumptions, Crawford-Brown ignored his own

stated principles of risk assessment. He testified that the "risk assessment community recognizes" that "all relevant lines of inference[170] should be examined, and then there should be a study done of the coherence across those lines of reasoning." Id. at 3200. He further testified that a "complete exposure assessment would look at all lines of reasoning." Id. at 3182. In addition, he testified that in making an exposure assessment, he would make an assessment of the strengths and weaknesses of the available evidence. He testified as follows at his deposition:

> Science can't distinguish between the estimates. What it can say is something about the relative strength of each of the estimates — which ones you believe and which ones you disbelieve, to what degree do you believe them or disbelieve them.
>
> And then, in my work, anyway, that is then called a cumulative confidence distribution. You ask, now considering all the lines of reasoning, how confident are you that it's less than one rem, ten rems, a hundred rems, a thousand rems, and so forth. And that assignment of confidence at any given dose [estimate] depends on how much you're weighing the various lines of evidence.

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170. In epidemiology, inference is "[t]he intellectual process of making generalizations from observations. In statistics, the development of generalization from sample data, usually with calculated degrees of uncertainty." REFERENCE MANUAL ON SCIENTIFIC EVIDENCE, at 174.

Id. at 3108-09. However, he did not assign any confidence to any of the assumptions he relied upon. Rather, he explained that his testimony "really is . . . not a statement about the complete coherence of all bodies of data, which I think ultimately need to go into an assessment of the exposure. And I've left that to others in this process to integrate together. I don't see that as my role here." Id. at 3182.

Crawford-Brown's failure to assess the validity of the opinions of the experts he relied upon together with his unblinking reliance on those experts' opinions, demonstrates that the methodology he used to formulate his opinion was flawed under Daubert as it was not calculated to produce reliable results. Thus, the District Court did not abuse its discretion in excluding Crawford-Brown's testimony.

4. Effect of the Exclusion of Wing's Lung Cancer Testimony.

A trial court is not precluded from granting summary judgment merely because expert testimony is admitted. If, even given the proffered expert testimony, the proponent "still has failed to present sufficient evidence to get to the jury," summary judgment is appropriate. Heller, at 152 (citing Daubert, at 596, 113 S.Ct. 2786); see also Paoli II, at 750 n. 21. Earlier, we concluded that the District Court abused its discretion by excluding the lung cancer portion of Steven Wing's cancer incidence study. Consequently, we must determine whether the improperly excluded expert testimony is sufficient to create a material issue of fact. Heller, at 152. See In re TMI Litigation Consolidated Proceedings, 927 F.Supp. 834 (M.D.Pa.1996).[171]

171. The District Court's summary judgment opinion.

Appendix A

The District Court's grant of summary judgment in favor of the defendants was the inevitable result of its exclusion of the testimony of the Trial Plaintiffs' dose exposure witnesses. At the conclusion of the Daubert challenges to the dose experts, the Trial Plaintiffs' dose exposure testimony rested upon the admissible testimony of four witnesses. The District Court identified them and summarized their admissible testimony as follows:

> [T]he Lochbaum testimony that a blowout may or may not have occurred, and that if one did occur, more than 10 million curies of noble gases were released from the plant during the accident; Dr. Vergeiner's testimony regarding how prevailing weather conditions may have effected plume dispersion and travel during the accident; Dr. Wing's cancer incidence study; and Professor Shevchenko's cytogenetic analysis and tree study.

927 F.Supp. at 863.

The court held that Trial Plaintiffs had to produce evidence demonstrating that "it is more likely than not that each of the Trial Plaintiffs' neoplasms were the result of their exposure to ionizing radiation during the TMI accident, in order to create a genuine issue of material fact." Id. at 866-87. Because the Trial Plaintiffs elected to try their cases on the theory that they were exposed to equivalent doses of at least 10 rems each, they had to produce evidence of that degree of exposure. The District Court reasoned that the crucial causation issue was the Trial Plaintiffs' ability to produce admissible source term[172] evidence. Id. at 867.

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172. See p. 671 supra.

However, at the time of the summary judgment motions, the Trial Plaintiffs had no admissible source term evidence. Id.

The only possible source term evidence was Lochbaum's equivocal "blowout" testimony, which the District Court had earlier determined would be admissible only if the Trial Plaintiffs' other experts could demonstrate that significant amounts of radionuclides were released as a result of the accident. 922 F.Supp. at 1052. However, because of earlier exclusionary rulings there was no other admissible source term evidence, and, consequently, the District Court found that "there is insufficient dose evidence . . . to make Lochbaum's testimony helpful to the trier of fact." 927 F.Supp. at 867. The District Court also found that Lochbaum's blowout testimony was so equivocal that it "lacked the certainty of a professional judgment" and was, "therefore, insufficient to defeat a motion for summary judgment."[173] Id. at 868. Consequently, the District Court found that the Trial Plaintiffs did not demonstrate that the reactor accident released high concentrations of radioactive materials to the environment. Id. In brief, the Trial Plaintiffs had no evidence that they were exposed to 10 rems of ionizing radiation and, therefore, there was no material factual dispute in regard to causation.

The admission of Wing's lung cancer testimony would not change that result. It is important to remember not only

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173. The Trial Plaintiffs' do not challenge the District Court's exclusion of Lochbaum's testimony or its finding that his testimony would not be sufficient to defeat the defendants' summary judgment motion. In fact, his name is only mentioned in passing. Trial Plaintiffs Br. at 14 n. 24.

that the District Court found that the "all cancer" and "leukemia" portions of Wing's cancer incidence study were admissible and that the court considered that testimony in its summary judgment analysis. The problem with Wing's cancer incidence study is that Wing assumed high levels of radiation exposure, see App. Vol. VIII, at 6871, and he therefore attributed the elevated cancer rates to that assumed exposure. But, as a result of the exclusionary rulings, there was no evidence of record to support Wing's assumption of high levels of radiation releases. Furthermore, Wing admitted at the in limine hearing that if the radiation levels were as postulated in the Hatch/Susser study, then he would not be able to make a causal connection between the accident releases and the elevated cancer rates. Id. at 7276-77. Consequently, the District Court ruled because the Trial Plaintiffs could not support Wing's assumption of high levels of radiation releases, "the Wing cancer study does nothing to assist Plaintiffs in creating a material factual dispute or meeting their burden of proof." 927 F.Supp. at 869. Even though we disagree with the exclusion of Wing's lung cancer testimony, we agree with that conclusion.

Consideration of Wing's improperly excluded lung cancer testimony would not create a genuine issue of material fact. If all of his cancer and leukemia testimony could not defeat a summary judgment motion, we are at a loss to see how a consideration of his lung cancer testimony would defeat that motion. Wing's lung cancer testimony is based on an assumption of high levels of radiation exposure which the Trial Plaintiffs were not able to prove. Consequently, Wing's lung cancer testimony would not create an issue of fact. Although exclusion of the lung cancer testimony was

an abuse of discretion, its admission would not change the ultimate outcome.

5. Exclusion of Experts' Submissions as Untimely.

The Trial Plaintiffs argue that the District Court committed reversible error by refusing to consider "vast amounts of plaintiffs' expert evidence, on the basis of untimeliness." Trial Plaintiffs' Br. at 59. However, with the exception of a brief discussion of the District Court's decision not to allow Shevchenko to testify about the results of a FISH study,[174] Id. at 66, the Trial Plaintiffs have not specifically

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174. For a discussion of the FISH methodology, see p. 691 n. 127, supra. In regard to the exclusion of Shevchenko's testimony of the FISH study, the district court noted:

> Neither Professor Shevchenko nor Dr. Snigiryova analyzed the TMI blood samples using the FISH method prior to the November 1995 in limine hearings. Their reports indicate that they are presently re-analyzing the blood samples using the FISH method, and that these results will validate their findings from the general cytogenetic analysis. This argument distorts the letter and spirit of the Federal Rules of Civil Procedure beyond recognition. Final reports of Plaintiffs' dose experts, containing a complete statement of the methodologies employed and the basis for the opinions, were due March 1, 1995. Had Plaintiffs produced the actual findings of a study using the FISH method on the TMI blood samples at the November in limine hearings, the court would likely have admitted those findings and allowed Defendants wide latitude to cross-examine. That Plaintiffs only recognized the importance of conducting

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identified what "vast amounts" of evidence they claim the District Court refused to consider. Nor have they attempted to explain how the court's alleged refusal affected either the admissibility determinations or the court's summary judgment decision.

It is clear that the District Court excluded a number of Trial Plaintiffs' experts' filings as a sanction for counsels' discovery violations. Apparently, the Trial Plaintiffs' counsel's filing of untimely expert reports was a recurring problem in this litigation.

On November 9, 1995, the District Court excluded the testimony of a number of experts because their reports were untimely filed. No memorandum of law explaining that order was issued concurrently with the order. However, on January 5,1996, the District Court filed an opinion which, inter alia, explained the reasons for the November 9, 1995, order. See In re TMI Litigation Cases Consolidated II, 911 F.Supp. 775, 828 (M.D.Pa.1996). There, the District Court noted that its order of November 13, 1994, directed the disclosure of Trial Plaintiffs' expert reports on dose to be filed by March 1, 1995. Id. According to the court, "some eight months later and without an explanation, Plaintiffs attempted to introduce new reports for a total of ten experts. Moreover, the bulk of

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> the FISH analysis after the filing deadlines passed is not sufficient justification for admitting such evidence one year after the filing deadline and four months after the in limine hearings on dose concluded.

922 F.Supp. at 1013.

these reports were to be delivered by previously unidentified experts." Id. Noting that "[f]or litigation purposes, the facts of this case must at some point become complete," the District Court felt compelled to "draw . . . a line in the sand." Id. at 828-29. Accordingly, it concluded that by March 1, 1995, "the discrete body of factual evidence with respect to the issue of dose became fixed. . . ." Id. at 829. Therefore, it held that any attempts "to build on this body of facts" after March 1, 1995, were misplaced and, consequently, it excluded the untimely reports. Id.

Despite the court's clear warning, and the equally distinct line that had been drawn, Trial Plaintiffs' counsel persisted in filing reports after deadlines had passed. We are normally reluctant to rely on lengthy excerpts from a District Court's opinion to facilitate our own, independent resolution of an appeal from that court's rulings. However, the chronology of the various case management orders and discovery orders is crucial to a complete understanding of the District Court's reasons for imposing the sanction of exclusion of evidence. Accordingly, we set forth at length the following excerpt from the District Court's opinion dated April 2, 1996. It details the chronology and places Trial Plaintiffs' claims in perspective.

> Defendants have objected, both in their filings and during the in limine hearings, to the admission of supplemental expert reports filed by Plaintiffs subsequent to the court ordered filing deadlines. For the most part, the court has avoided piecemeal rulings on this issue opting instead to make one uniform ruling. The issue is now ripe for

disposition. A brief background discussion will place matters in context.

A. Case Management History

The timeliness issue has recurred in many settings within this litigation and has been particularly troubling to the court. Historically, the court has encountered significant difficulty in keeping the parties adhered to any case management order. As a result, there have been close to a dozen "case management orders." 7/10/92 Proposed Schedules of Plaintiffs and Defendants for Taking Cases to Trial; 6/15/93 Case Management Order (setting jury selection for 7/6/94); 11712/93 Revised Case Management Order (moving jury selection to 10/3/94 at the request of parties); 5/13/94 Order Amending Case Management Schedule (moving jury selection to 4/13/95); 7/28/94 Order (granting Plaintiffs' request for further amendment of pre-trial schedule); 10/14/94 Order (further amending pre-trial schedule at Plaintiffs' request, and noting that absent extreme and compelling circumstances no further amendments will be entertained); 10/19/94 Order (directing parties to submit final joint case management schedule in response to correspondence from counsel); 11/3/94 Order (adopting parties' final joint case management schedule, noting that said order is binding and that it will not be amended absent extreme and compelling circumstances); 5/8/95 Order (moving jury selection to 6/3/96). Much to

its own detriment, the court has been flexible and accommodating with respect to the pre-trial schedule.

In November 1994, having grown weary of the parties' inability to comply with set deadlines and fearing that the instant action would languish, the court ordered the parties to draft a final joint case management schedule. On November 3 the court adopted the schedule proposed by the parties and again indicated that the schedule would not be altered absent extreme and compelling circumstances. On May 8, 1995, the court issued an order supplementing the November 1994 case management order to place the case on the June 1996 trial list. Since the entry of the May 8 order, the court, although permitting minor alterations to the schedule, has denied any motion to amend that would effectively remove the case from the June 1996 trial list.

The captioned action, involving approximately 2,000 Plaintiffs, was consolidated under one case number in 1988. To an extent, circumstances beyond the court's control, such as the filing of interlocutory appeals and Congress's amendment of the Price Anderson Act, have stymied the prompt resolution of this action. Nevertheless, a review of the docket reveals that the test cases's torpid progression toward trial is due in part to the parties' willingness to stipulate to extensions of time and alterations of the case management

schedule and the court's historical willingness to accommodate such requests.

B. Plaintiffs' Expert Reports

Defendants object to the admission of all of Plaintiffs' expert reports and supplemental affidavits filed subsequent to the court ordered filing deadlines. Although tedious, the following review of Plaintiffs practice in filing expert reports is warranted.

Pursuant to an order dated May 13, 1994, Plaintiffs were to file the expert reports of James Gunckel, Richard Webb and Ignaz Vergeiner not later than August 1, 1994. This order also directed that expert reports on medical causation were to be filed not later than September 1, 1994 and that expert reports on punitive damages were to be filed not later than October 1, 1994. On August 1, 1994, Plaintiffs filed the 6/94 report of Ignaz Vergeiner ("TMI Treatise 1"), and the 5/26/94 and 8/1/94 affidavits of Douglas Crawford-Brown. On August 4, 1994, Plaintiffs filed the 8/1/94 preliminary report of Richard Webb entitled "A Preview Short Synopsis." Thus, the report of James Gunckel was not timely filed on August 1, and the August 4 filing of the Webb "Preview" was both untimely and in contravention of Rule 26(a)(2) of the Federal Rules of Civil Procedure ("The report shall contain a complete statement of all opinions to be expressed and the basis and

reasons therefor . . ."). The court was remiss in not striking these filings immediately and, in temporarily overlooking these rule violations, the court may have unwittingly encouraged Plaintiffs' improper conduct. The record reflects that these 1994 filings were only the first in a long stream of improper and untimely filings.

On September 15, 1994, one and one-half months after the filing deadline, Plaintiffs filed the 7/6/94 Affidavit of Vladimir Shevchenko. On November 3, 1994, the court entered the final joint case management schedule. This schedule extended the deadline for Plaintiffs' filing of dose and medical causation expert reports to March 1, 1995. On March 1, Plaintiffs filed the expert "reports" of the following experts: Armentrout, Crawford-Brown, Gunckel, Hinrichesen, Lochbaum, Shevchenko, Vergeiner, Webb, Wing, Fajardo, Winters, Zakrzewski. On March 14, without leave of court, Plaintiffs supplemented their March 1 filing with the reports of Shevchenko, Tascaev, Kozubov, Popov, Portman, Tarasenko, and Snigiryova. On March 15, again without leave of court, Plaintiffs supplemented their March 1 filing with the report of Bruce Molholt. Finally, on March 29, without leave of court, Plaintiffs filed a third supplement to the March 1 filing adding to the reports of Shevchenko and Zakrzewski. Thus, as of April 1995, Plaintiffs had late-filed a significant portion of their expert reports on dose and medical causation.

Appendix A

In February 1995, the court issued a preliminary memorandum of law related to Defendants' motion in limine to exclude Dr. Molholt's 4/8/93 report, and ordered limited additional briefing with respect to certain of the Paoli II factors. In re TMI, Mem. Op. at 22 (M.D.Pa. February 14, 1995) ("[T]he court has invited the parties to respond concisely to the issues raised . . . this is not an invitation to deluge the court with paper. Clear, concise, relevant information will assist the court in reaching a just resolution; likewise, the submission of frivolous or irrelevant information will be frowned upon.") As exhibits to their court-ordered filing, Plaintiffs submitted several new expert reports (5/1/95 Molholt; 4/24/95 Kerman; 5/2/95 Kerman; 2/27/95 Crawford-Brown). In September 1995, Plaintiffs, again without leave of court, untimely filed the reports of Theodore Sterling and Ronald Kerman.

The next battery of Plaintiffs' expert reports were filed as exhibits to their opposition to Defendants' motion in limine to exclude Plaintiffs' dose experts. On October 25, Plaintiffs filed as exhibits the updated reports of the following experts: Vergeiner (two separate affidavits dated 10/18/95), Armentrout (10/10/95 Aff.; 10/22/95 Aff.), Gunckel (8/23/95 Aff.), Shevchenko (10/6/95 Aff.), Wing (10/19/95 Aff.), Crawford-Brown (10/20/95 Aff.), Molholt (9/8/95 Aff.; 9/14/95 Aff.). On October 31, with leave of the

court,[175] Plaintiffs' supplemented the record with the following affidavits/new reports: Armentrout (9/20/95 Aff.; 5/11/95 Aff.), Blanch (10/31/95 Aff.), Kerman (10/30/95 Aff.), King (10/30/95

175. The district court explained that it re-opened discovery for the following reason: Through a Memorandum and Order dated October 19, 1995, the court re-opened discovery from October 20 to October 30 for the purpose of granting Plaintiffs access to original plant data stored at the Emaus Street repository. The court granted Plaintiffs motion to compel despite the fact that "[a]fter sitting on their right to access these materials for nearly one decade, Plaintiffs now, one week before their brief on the in limine issues is due and after the formal close of discovery, request that Defendants be compelled to produce the aforementioned documents merely because it would not be inordinately difficult for Defendants to do so." 10/19/95 Order at 3. Plaintiffs offered the court no explanation as to why they had failed to view this material during the formal discovery period. Id.

Pursuant to its granting the motion to compel, the court allowed Plaintiffs "to supplement their brief in opposition to Defendants' motion in limine." The court allowed Plaintiffs to supplement the record to the extent that something in the original strip chart data proved helpful to their case. Plaintiffs were not granted permission to supplement the record with anything beyond the scope of the "new" original plant data.

922 F.Supp. at 1003 n. 7.

> Aff.), Reyblatt (10/31/95 Aff.), Shevchenko (10/6/95 Aff.), Kozubov (9/12/95 Aff.), Smirennyi (10/30/95 Aff.), Wing (10/27/95 Aff.). On January 16, 1996, as exhibits to a brief in opposition to Defendants' motion to compel, Plaintiffs filed the following supplemental affidavits: Crawford-Brown, Ornstein, Purcell, Reyblatt. Finally, during February 1996, Plaintiffs filed the following supplemental affidavits without leave of court: Wing (10/19/95 Aff.; 1/26/96 Aff.; 1/31/96 Aff.; 2/7/96 Aff.), Kozubov (1/30/96 Aff.), Armentrout (2/1/96 Aff.), Milhollin (5/5/96 Aff.), Griffin (1/30/96 Aff.), King (2/16/96 Aff.).

In re TMI Litigation Cases Consolidated II, 922 F.Supp. 997, 1000-03 (M.D.Pa.1996), (original footnotes omitted).

The District Court concluded that Trial Plaintiffs' repeated untimely filings of experts' reports provided adequate grounds to exclude reports filed without leave of court subsequent to court ordered filing deadlines. Id. at 1007. Realizing, however, that the exclusion of all untimely filed reports "would result in the effective dismissal of much of the Plaintiffs' case" and, was, therefore, "unduly harsh" to the Trial Plaintiffs who had nothing to do with their counsel's disregard of court orders, the District Court sought to seek the via media between a blanket exclusion and its concern that Trial Plaintiffs not pay too dear a price for the conduct of their attorneys. Id. It referred back to its aforementioned January 5, 1996, order and opinion, and reasoned that after publication of that order and opinion,

"there could be no question" that continued filing of expert submissions without leave of court was prohibited. Id. at 1008. Accordingly, it decided to exclude all supplemental affidavits filed after January 5, 1996. However, it allowed all supplemental affidavits and reports filed after to March 1, 1995, but prior to January 5, 1996, whose admissibility had not yet been ruled upon.[176] Id.

Federal Rule of Civil Procedure 37(b)(2)(B) authorizes the District Court to sanction a party's failure to comply with a discovery order by "prohibiting that party from introducing designated matters into evidence." Although the exclusion of evidence for violation of a discovery order is an "extreme sanction," Dudley v. South Jersey Metal, Inc., 555 F.2d 96, 99 (3d Cir.1917), the "trial court's exclusion of testimony for failure of counsel to adhere to a pretrial order will not be disturbed on appeal absent a clear abuse of discretion." Semper v. Santos, 845 F.2d 1233, 1237 (3d Cir.1988). In Paoli II, at 791, we recognized the continuing applicability of Meyers v. Pennypack Woods Home Ownership Ass'n, 559 F.2d 894 (3d Cir.1977) to a Rule 37 exclusion analysis. In Pennypack, we listed certain factors which must be considered in evaluating whether the District Court properly exercised its discretion. They are:

> (1) the prejudice or surprise in fact of the party against whom the excluded witnesses would have

176. The District Court also issued an order to show cause why monetary sanctions should not be imposed against certain of Trial Plaintiffs' counsel. On August 7, 1996, the district court entered an order imposing monetary sanctions against counsel. That order is the subject of Appeal No. 96-7625, discussed infra.

> testified, (2) the ability of that party to cure the prejudice, (3) the extent to which waiver of the rule against calling unlisted witnesses would disrupt the orderly and efficient trial of the case or of other cases in the court, and (4) bad faith or willfulness in failing to comply with the district court's order.

559 F.2d at 904-05. The District Court applied the Pennypack factors here and concluded that

> (1) Defendants would be prejudiced by the admission of certain of the untimely reports insofar as the rigorous pre-trial schedule precludes them from having sufficient time to prepare to cross-examine on the late-filed reports; (2) Defendants are unable to cure the prejudice insofar as the court is unwilling to further alter the pre-trial schedule because such alteration would necessitate postponing the trial date; (3) waiver of the Rule 37 sanctions would disrupt the orderly trial of this case as well as a multitude of other cases on the court's docket; and (4) Plaintiffs repeated violation of numerous orders of this court, failure to seek leave of court before filing untimely reports, and "covert" filing of additional reports as exhibits to a variety of unrelated motions rather than "overtly" making supplemental filings, rises to the level of bad faith.

922 F.Supp. at 1004.

We agree with the court's analysis. Accordingly, we do not believe that the District Court abused its discretion in imposing the sanction of exclusion under Rule 37. All of the reports which defendants sought to exclude were filed after the formal close of discovery. Discovery in this litigation was open for nearly one decade. Trial Plaintiffs' counsel can hardly complain that they had inadequate time to provide the desired reports, nor can they claim that the exclusion of the late reports in response to their practice of continually ignoring District Court deadlines caught them by surprise. Counsel's failure to comply with the deadlines imposed by the District Court is inexcusable. The District Court recognized it as such, and responded appropriately.

Although it appears from the record that the defendants knew the identity of the expert witnesses in a timely fashion, the record also shows that the substance of the experts' reports was not known to the defendants. Many of the timely reports have little, if any, resemblance to the supplemental initial reports which the Trial Plaintiffs subsequently filed. For example, Molholt's March 13, 1995 and May 1, 1995 reports differ in a number of significant ways from his initial April 8, 1993 report. Furthermore, experts' submissions continued to be made up to, during, and even after, the in limine hearings.

In Paoli II, the District Court precluded a physician from testifying about a medical monitoring program that he thought the plaintiffs should undergo because counsel did not timely submit a Fed.R.Civ.P. 26(b)(4) statement detailing the substance of the physician's testimony about the monitoring program. We found that to be an abuse of

discretion because the failure to timely file was only a "slight deviation from pre-trial notice requirements, and admitting the witness was likely to cause only slight prejudice to the defendants, who were already aware of the basic substance of the witness' testimony." Paoli II, at 792. However, the considerations which led us to find an abuse of discretion in Paoli II are not present here. Here, the District Court was faced with a pattern of filings that constituted a flagrant violation of pre-trial orders. The pattern was as persistent as it was unjustified. The District Court's exclusion under Rule 37 was well within its discretion.

6. Conclusion.

Earlier in our discussion we noted that although the Trial Plaintiffs appeal from the District Court's grant of summary judgment to the defendants, they do not argue that the grant of summary judgment was improper in view of the court's admissibility decisions on their dose experts. In other words, they do not argue that the District Court erred when it found that the admissible expert testimony of Vergeiner, Shevchenko and Wing was insufficient to create a genuine issue of material fact. Consequently, our inquiry has focused on the propriety of the District Court's gate-keeping role under Daubert and not on the standards governing the grant of summary judgment. As we explained earlier, we need to decide whether the improperly excluded testimony created a genuine issue of material fact only if we determined that the District Court erred in its Daubert analyses of the proffered experts.

However, with the exception of Wing's lung cancer testimony, we have found that the District Court's

admissibility determinations were well within its discretion as a gatekeeper. We have also determined that the improper exclusion of Wing's lung cancer testimony does not create a genuine issue of material fact. Finally, we have found that the District Court did not abuse its discretion by excluding evidence under Fed.R.Civ.P. 37(b)(2)(B). Therefore, we will affirm the District Court's grant of summary judgment in favor the defendants and against the Trial Plaintiffs.

B. The Non-Trial Plaintiffs' Appeal.

As we noted in the Procedural History portion of this opinion, the District Court held that its decision on the defendants' summary judgment motion directed to the Trial Plaintiffs would be binding on all plaintiffs to the extent that the Trial Plaintiffs' ruling turns on broad evidentiary issues common to all plaintiffs. See In re TMI Litigation Consolidated Proceedings, 927 F.Supp. 834, 838 (M.D.Pa.1996). Consequently, when the District Court held that the Trial Plaintiffs could not present dose evidence sufficient to resist summary judgment, it extended that holding to all plaintiffs. The court held:

> Because the court finds the quantum of evidence on the issue of dose to be insufficient, and because no Plaintiff will be able to state a prima facie case without adequate dose evidence, the instant ruling is binding on all Plaintiffs.

Id. at 838.

Not unexpectedly, the Non-Trial Plaintiffs contend that the extension of the Trial Plaintiffs' summary judgment

decision to them was improper. In support of that contention, they make a number of arguments, viz., (1) that their cases were consolidated for administrative purposes only; (2) that ¶3 of the Stipulation is a clear reservation of rights that there would not be a consolidated trial that binds all plaintiffs; (3) that the Non-Trial Plaintiffs have the right to present different proofs, experts and theories of recovery than those presented by the Trial Plaintiffs; (4) that this is not a class action and they were never given the opportunity to "opt-out" of a consolidated trial; (5) that it is unfair to extend the discovery sanctions imposed against the Trial Plaintiffs against them; (6) that they never agreed that they had to demonstrate that they were exposed to 10 rems or more of radiation in order establish causation; and (7) personal injury causation is a highly individualized question which needs to be determined in a case-by-case basis.

The defendants contend that the District Court's extension of the summary judgment to the Non-Trial Plaintiffs was correct. They argue that because of consolidation, the case management orders governing discovery and all pre-trial proceedings applied to all plaintiffs, both trial and non-trial.[177] They reason that

177. Defendants also argue that it is clear "that summary judgment can be entered in cases consolidated for pretrial purposes, and result in the termination of all of the consolidated cases." Appellees' Br. at 14. In support of that proposition, they rely on our opinion in In re Donald J. Trump Casino Sec. Litig.-Taj Mahal Litigation, 7 F.3d 357, 367 (3d Cir.1993), cert. denied, 510 U.S. 1178, 114 S.Ct. 1219, 127 L.Ed.2d 565(1994), where we held that transferred cases consolidated for pretrial purposes under the

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inasmuch as summary judgment is a pre-trial proceeding, it therefore applied to all of the plaintiffs, and the extension of the summary judgment decision was therefore a natural result of the consolidation order.

However, we believe that both sides to this appeal have failed to see some essential issues which mitigate against the extension of the summary judgment motion to the Non-Trial Plaintiffs. The primary inquiry should be determining the effect of consolidation on the substantive rights of the parties in the consolidated cases. The TMI plaintiffs' cases were consolidated under Rule 42(a), which provides:

> When actions involving a common question of law or fact are pending before the court, it may order a joint hearing or trial of any or all the matters in issue in the actions; it may order all the actions consolidated; and it may make such orders concerning proceedings therein as may tend to avoid unnecessary costs or delay.

Fed.R.Civ.P. 42(a). The purpose of consolidation is "to streamline and economize pretrial proceedings so as to avoid duplication of effort, and to prevent conflicting outcomes in cases involving similar legal and factual issues." In re

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28 U.S.C. § 1407 can be terminated by a transferee court under Rule 12(b)(6). However, Trump does not apply here because § 1407 concerns multidistrict litigation and, more importantly, the parties in all of the cases transferred under § 1407, were before the District Court that granted the pre-trial dispositive motions.

Prudential Securities Inc. Ltd. Partnerships Litigation, 158 F.R.D. 562, 571 (S.D.N.Y.1994). Consolidation, however, is only a matter of "convenience and economy in administration." Johnson v. Manhattan R. Co., 289 U.S. 479, 497, 53 S.Ct. 721, 77 L.Ed. 1331 (1933).[178] Consolidation "does not merge the suits into a single cause, or change the rights of the parties, or make those who are parties in one suit parties in another." Id.

We have not had many occasions to cite Johnson v. Manhattan R. Co. in our prior opinions. In Bradgate Associates v. Fellows, Read & Associates, Inc., 999 F.2d 745, 750 (3d Cir.1993), we noted that although consolidated cases are heard together, "they are not necessarily merged forever and for all purposes." There, commenting on Johnson, we wrote:

> Johnson cautions that while consolidated cases may be treated as one lawsuit in order to conserve judicial resources, the procedure should not impose the heavy toll of a diminution of any party's rights.

Id. (emphasis added). The facts in Bradgate, while admittedly not at all like the facts here, nonetheless demonstrate that consolidation is not intended to affect the substantive rights of the parties to the consolidated cases.

The parties in Bradgate were Bradgate Delaware and Bradgate New Jersey, both of which were real estate

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178. Consolidation in Johnson was made pursuant to 28 U.S.C. § 734, a precursor to Fed.R.Civ.P. 42.

development firms. The former was a Delaware corporation, and the latter was a New Jersey corporation. Presumably, both were part of Bradgate Associates. Fellows, Read was a New Jersey engineering firm that had contracted with either Bradgate Delaware or Bradgate New Jersey to provide engineering services. A controversy arose and Fellows, Read sued Bradgate Delaware in New Jersey state court to recover payment for services rendered. Bradgate Delaware responded by filing a federal lawsuit in New Jersey alleging fraud, negligence and breach of contract and removing Fellows, Read's state suit to federal court where the state and federal cases were consolidated.

Bradgate Delaware alleged in its federal complaint and its removal petition that diversity existed because Bradgate Delaware was the successor in interest to Bradgate New Jersey. The latter was the entity which Fellows, Read claimed was the real party in interest in the engineering services contract. Fellows, Read challenged Bradgate Delaware's diversity allegations claiming that Bradgate New Jersey was still a viable corporate entity and that Bradgate Delaware had not succeeded to Bradgate New Jersey's interests. Thus, according to Fellows, Read, diversity did not exist, and the district court had no subject matter jurisdiction. For reasons not relevant here, the district court agreed that it had no diversity jurisdiction and remanded both the original federal action and the removed state action back to New Jersey state court. Fellows, Read appealed the district court's decision to remand that portion of the case which was originally filed in federal court.

We found that a remand of both cases was error that prejudiced Fellows, Read. We reasoned that finding an

absence of diversity terminates a case originally filed in federal court. But, a finding of lack of subject matter jurisdiction does not extinguish a removed state court case. The state court case is simply remanded to state court. However, the district court, "diminished Fellows, Read's rights by prolonging litigation over claims which should have been dismissed," by remanding both cases to state court, instead of dismissing the federal court case and remanding only the state court case. Id. at 751. The proper procedure the district court should have followed was to "apply the rules pertaining to dismissal and remand as if the cases had retained their separate identities and had never been consolidated." Id.

Admittedly, Bradgate and the Non-Trial Plaintiffs' appeal here are not remotely similar. In fact, the result in Bradgate is the exact opposite of the result here. That is, while the court was forcing Fellows, Read to litigate a case it should not have had to litigate, the District Court here was denying the Non-Trial Plaintiffs the opportunity to litigate the cases they wanted to litigate. Nevertheless the principle underlying Bradgate, i.e., that consolidation cannot affect the substantive rights of the parties to the consolidated cases, is applicable to the Non-Trial Plaintiffs' consolidated cases, and is consistent with our application of Johnson.

It is beyond dispute that the District Court's extension of the Trial Plaintiffs' summary judgment decision to the Non-Trial Plaintiffs' claims adversely affected the substantive rights of the Non-Trial Plaintiffs. However, under Johnson and Bradgate, the District Court could not properly extinguish the substantive rights of the 1,990 Non-Trial

Plaintiffs merely because all of the cases had been consolidated.

Upon close examination, the TMI Non-Trial Plaintiffs and Trial Plaintiffs are even more separated than the plaintiffs in Bradgate because the Non-Trial Plaintiffs were not even litigating their claims and not presenting arguments to the District Court. The TMI personal injury litigation here involves a "test plaintiff" approach to trying a mass tort case. However, there is nothing here to indicate that the Non-Trial Plaintiffs were given an opportunity to object the defendants' motion for summary judgment or otherwise protect their substantive claims.

Moreover, Rule 42(b) states:

> The court, in furtherance of convenience or to avoid prejudice, or when separate trials will be conducive to expedition and economy, may order a separate trial of any claim, cross-claim, counterclaim, or third-party claim, or of any separate issue or of any number of claims, cross-claims, counterclaims, third-party claims, or issues, always preserving inviolate the right of trial by jury as declared by the Seventh Amendment to the Constitution or as given by a statute of the United States.

Fed.R.Civ.P. 42(b) (emphasis added). The extension of the summary judgment decision to the Non-Trial Plaintiffs implicates their Seventh Amendment jury trial rights. Summary judgment does not violate a party's Seventh

Amendment jury trial rights so long as the person having the right to the jury trial is an actual participant in the summary judgment proceeding. See City of Chanute, Kansas v. Williams Natural Gas Co., 955 F.2d 641, 657 (10th Cir.1992) ("[S]ummary judgment, applied properly, does not violate the Seventh Amendment.") (citing Fidelity & Deposit Co. v. United States ex rel. Smoot, 187 U.S. 315, 319-21, 23 S.Ct. 120, 47 L.Ed. 194 (1902)). However, absent a positive manifestation of agreement by Non-Trial Plaintiffs, we cannot conclude that their Seventh Amendment right is not compromised by extending a summary judgment against the Trial Plaintiffs to the non-participating, non-trial plaintiff. In fact, a Seventh Amendment argument was made in the District Court, but the argument was summarily dismissed. 927 F.Supp. at 838 n. 7.

The District Court's extension of the Trial Plaintiffs' summary judgment decision to the Non-Trial Plaintiffs would also improperly extend the doctrine of collateral estoppel/ issue preclusion. See DeLuca v. Merrell Dow Pharmaceuticals, Inc., 911 F.2d 941 (3d Cir.1990). In DeLuca, we commented on a defense theory that a group of consolidated Bendectin cases should be dismissed because of positive outcomes for Bendectin defendants in other cases. We said:

> [W]e do not have the authority to create special rules to address the problems posed by continued Bendectin litigation. Principles of issue preclusion have not developed to the point where we may bind plaintiffs by the finding of previous proceedings in which they were not parties, even by a proceeding as thorough as the multidistrict common issues trial.

Id. at 952. Although DeLuca is distinguishable from the same as the Non-Trial Plaintiffs' case, the District Court's extension of the Trial Plaintiffs' summary judgment decision to the non-Trial Plaintiffs' claims implicates the issue preclusion concerns we found troublesome in DeLuca.

Finally, we believe that the District Court erred by holding that all plaintiffs had to present evidence that they were exposed to 10 rem or more of ionizing radiation in order "to establish causation on the basis of a specific radiation exposure level." 927 F.Supp. at 865. Based on its review of the scientific literature, Id. at 834; 844-45, the District Court found that there is a consensus in the scientific community that, at levels of exposure below 10 rem, the causal link between exposure and cancer induction is purely speculative. Id. at 865. Consequently, the court held that, faced with evidence of an equivalent exposure below 10 rem, "no rational jury . . . could find it more likely than not that radiation induced a given neoplasm." Id.

At exposure levels below 10 rem (100 mSv) or 10 rad (100 mGy), cancer risks are based on extrapolations from risks seen at higher exposure levels. See RADIATION DOSE RECONSTRUCTION, at 8 ("It is important to note that serious health effects of exposure to ionizing radiation, such as an increase in cancer, have not been observed directly at doses below 0.2 Gy (20 rad) among the survivors of the atomic bombing of Hiroshima and Nagasaki. The risks assumed to occur at doses below 0.2 Gy (20 rad) are, therefore, extrapolations from the risks seen at intermediate [0.2-2.0 Gy (20-200 rad)] and high [>2 Gy (>200 rad)] doses to doses above natural background radiation."); see also

MEDICAL EFFECTS, at 69 ("Virtually all of the data used to derive risk estimates for low-dose levels are obtained from situations in which the exposure level actually occurred at dose levels above 0.1 Gy (10 rad)."). However, the fact that risks of cancer from exposure at low doses are based on extrapolations from higher doses does not mean that the scientific community believes that there is no causal connection between a low-level exposure and cancer induction. We do not believe that the scientific community views that connection to be speculative. Rather, as noted above, at very low doses it is possible that ionizing radiation may deposit sufficient energy into a cell to adversely modify it. ICRP, at 98. Indeed, scientists assume that there is no threshold for the induction of cancer. MEDICAL EFFECTS, at 69. In other words, ionizing radiation can cause cancer even at the lowest doses, and therefore it has to be taken into account at all dose levels. ICRP, at 67.

The Non-Trial Plaintiffs ought to be able to attempt to establish that doses below the threshold selected by Trial Plaintiffs has induced their neoplasms, or caused their pathologies. Accordingly, we conclude that it was error for the District Court to hold that all the plaintiffs had to demonstrate an exposure of at least 10 rem to satisfy their burden of establishing causation. By doing so, the District Court was, in effect, deciding, contrary to the opinions of the scientific community, that 10 rem was the threshold for cancer induction, and that exposure to lesser doses of ionizing radiation could not reasonably be believed to cause cancer.[179]

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179. Although, as noted in our discussion of the physics involved here, many observations of atomic behavior lead to

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Appendix A

The District Court's finding that all plaintiffs had to demonstrate an equivalent dose exposure of 10 rem or more did not affect the outcome of the Trial Plaintiffs' cases because, as noted earlier, they proceeded on the theory that they were exposed to at least that equivalent dose of ionizing radiation. The Trial Plaintiffs' medical causation experts premised their opinions that radiation was the cause of the test plaintiffs' neoplasms on their expectation that the dose exposure experts would demonstrate that the test plaintiffs were exposed to 10 rem or more of ionizing radiation. 927 F.Supp. at 862-863. Although discovery is closed as to all plaintiffs, we do not know anything about the trial theories of the Non-Trial Plaintiffs. We do not know whether they would also agree to proceed on the basis of an equivalent exposure of at least 10 rem. Moreover, we do not know the level of exposure the Non-Trial Plaintiffs' medical causation experts based their opinions on.

We also note that not only is there a statistical association between radiation and health effects, but also that a method for determining the likelihood of radiation-caused malignancy has been established by the National Council on Radiation Protection and Measurements. See NCRP 7. The Council has established a "probability of causation (PC) approach" for determining the probability (as opposed to absolute proof) that a particular malignancy may have been

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counter-intuitive conclusions, we nevertheless think that common sense alone mitigates against establishing a bright line threshold for safe irradiation. We do not believe, for example, that a person who has been exposed to 10 rem of radiation is at risk for developing a neoplasm, but someone exposed to 9.99 rem is not.

caused by exposure to ionizing radiation. Although the radiation dose to the individual is a variable in the PC equation, there is no specific dose required to make the equation workable.[180]

Accordingly, we hold that the District Court's extension of the summary judgment to the Non-Trial Plaintiffs was error, and we will reverse the grant of summary judgment to the defendants on the Non-Trial Plaintiffs' claims and remand for further proceedings.[181]

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180. We take no position as to whether an expert opinion as to tumor causation that is based upon the PC approach could withstand a Daubert challenge or a challenge under Rule 703. We note the PC approach here, however, as it demonstrates, at least one of the problems in the District Court's decision to hold Non-Trial Plaintiffs to the 10 rem threshold.

181. With regard to the claims of the Non-Trial Plaintiffs, we note that over 1,600 of them are represented by the law firms of Levin, Fishbein, Sedran & Berman, Esqs., and Hepford, Swartz & Morgan, Esqs. However, approximately 300 of the Non-Trial Plaintiffs are represented by The Tarasi Law Firm, P. C., and the remaining Non-Trial Plaintiffs are represented either by Shawn A. Bozarth, Esq., or Peter J. Neeson, Esq. On August 5, 1996, a Notice of Appeal was filed in the district court on behalf of all the plaintiffs, including the Non-Trial Plaintiffs. On October 31, 1996, Entries of Appearance were filed with the Clerk of Court by Levin, Fishbein, Sedran & Berman and Hepford, Swartz & Morgan on behalf of the appellants they represent, all of whom were specifically identified in the Entry of Appearance. On November 22, 1996, Lou Tarasi, Esq., of The Tarasi Law Firm, P. C., filed his Entry of Appearance on behalf of the appellants he represents, but no specific appellant was identified. No Entry of Appearance was filed by Shawn A.

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Appendix A

C. The Monetary Sanctions Appeal.

Trial Plaintiffs' counsel, Arnold Levin, Laurence Berman and Lee Swartz, appeal from the District Court's imposition of monetary sanctions against them in the amount of $500 each for violations of the mandatory disclosure requirements of Fed.R.Civ.P. 26(a) and for disregard of court orders issued pursuant to Fed.R.Civ.P. 26(f). This appeal

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Bozarth, Esq., on behalf of his clients, or by Peter J. Neeson, Esq., on behalf of his clients. A brief on behalf of the appellants represented by Levin, et al., and by Hepford, et al., was timely filed. However, no brief was filed on behalf of the appellants represented by The Tarasi Law Firm. Mr. Tarasi appears only on the Brief of the Levin and Hepford appellants as "Of Counsel for the Appellants Identified in the Entry of Appearance." No briefs were ever filed by Messrs. Bozarth and Neeson and their names do not appear on the brief filed by Levin, et al., and Hepford, et al.

The appellees filed a motion, under Fed.R.App. P. 31(c) and Third Circuit LAR 107.2(b), to dismiss the appeals of the appellants represented by Tarasi, Bozarth and Neeson based on their failure to file briefs. Mr. Tarasi responded by filing a motion to join in the brief filed by Levin and Hepford. Messrs. Bozarth and Neeson did not respond to appellees' motion to dismiss. On April 15, 1997, order was entered granting Tarasi's motion to join in the Levin and Hepford brief. However, the appellees' motion to dismiss was referred to the merits panel for disposition.

The April 15, 1997 order moots the motion to dismiss the appeal as to the Tarasi appellants. However, because Messrs. Bozarth and Neeson did not file briefs or in any way respond to the appellees' motion to dismiss, we will dismiss the appeals as to the appellants represented by them.

closely overlaps the Trial Plaintiffs' assertion that the District Court's exclusion of evidence under Fed.R.Civ.P. 37 was an abuse of discretion. As noted above, the District Court filed a well-reasoned and comprehensive Memorandum Opinion, dated August 7, 1996, explaining its rationale for the imposition of monetary sanctions against counsel. We can add nothing to that analysis. For the reasons we have already cited in our affirmance of the District Court's exclusion of evidence, we also hold that the District Court did not abuse its discretion by imposing monetary sanctions against counsel and we will affirm substantially for the reasons set forth in the District Court's August 7, 1996 Memorandum Opinion.[182]

D. Reassignment Upon Remand.

One matter remains. Plaintiffs' counsel seek reassignment of this case from Judge Rambo to another judge upon remand. They argue that the history of this case reflects "sharp exchanges between counsel and court" and "hostile rebukes of counsel by the court." Sanction's Br. at 44. However, as grounds for the requested reassignment, they assert:

> But, plaintiffs are not relying on such conduct in seeking reassignment. Rather, plaintiffs' contention is that the TMI district court's rulings show such a strong and unjustified displeasure with plaintiffs' counsel and disbelief in plaintiffs' experts and the case that a reasonable person,

182. We review the imposition of discovery sanctions for an abuse of discretion. Paoli II, at 750.

> knowing all of the facts regarding the district court's ruling, may well conclude that the judge is not impartial and cannot make objective rulings with respect to plaintiffs' case.

Id. This is counsel's second attempt to do an end run around Judge Rambo. In a petition for a writ of mandamus seeking reassignment which trial-plaintiffs' counsel filed after the District Court's in limine rulings, counsel alleged, inter alia, that Judge Rambo conducted "herself so as to create 'an appearance of a lack of impartiality that jeopardizes the credibility of her evidentiary and procedural rulings.' " See Dolan v. General Public Utilities, No. 96-7264, slip. op. at 3 (3d Cir. May 10, 1996). In our decision denying the writ we stated:

> The Supreme Court has made clear that "judicial rulings alone almost never constitute valid basis for a bias or impartiality motion." Liteky v. United States, 510 U.S. 540, 114 S.Ct. 1147, 1157, 127 L.Ed.2d 474 (1994). Thus, we have held "disagreement with a judge's determinations and rulings cannot be equated with the showing required to so reflect on impartiality as to require recusal." Jones v. Pittsburgh Nat'l Corp., 899 F.2d 1350, 1356 (3d Cir.1990). Petitioners' allegations amount to little more that disagreement with her legal rulings. Disqualification is not an appropriate remedy for disagreement over a legal ruling. In the event the court's evidentiary rulings may be in error, they are subject to review on appeal.

> Petitioners also assert Judge Rambo should be disqualified because she allegedly made remarks to counsel that demonstrate personal bias. But "opinions formed by the judge on the basis of facts introduced or events occurring in the proceedings, do not constitute a basis for a bias or partiality motion unless they display a deep-seated favoritism or antagonism that would make fair judgment impossible." Liteky, 114 S.Ct. at 1157. After an extensive review of the record we find no evidence of "deep-seated favoritism" in the remarks made by Judge Rambo.

Id. at 7.

In spite of this explanation of our reasons for denying counsel's initial attempt to get their case before a different judge, counsel reiterate the same arguments that we previously rejected in support of the instant appeal. A meritless legal position does not become meritorious merely by repeating it in a subsequent appeal. Plaintiffs' counsel have ignored our opinion in Dolan. In Dolan, we specifically stated that disqualification is not a "remedy" to an adverse judicial ruling. Trial counsel's arguments regarding assignment of a new judge have not changed since Dolan, but neither has the law. Counsel are really complaining about the substance of Judge Rambo's rulings against them. However, as we informed them in Dolan, adverse rulings do not warrant disqualification.[183]

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183. Moreover, we can not help but comment on the commendable manner in which Judge Rambo has handled this

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For the above reasons, we will affirm the district court's imposition of monetary sanctions and deny the request for reassignment.

VII. CONCLUSION

To restate our decision in each appeal, we will affirm the District Court's grant of summary judgment in favor of the defendants on the Trial Plaintiffs' claims and will affirm the District Court's imposition of monetary sanctions against certain of Trial Plaintiffs' counsel. We will reverse the grant of summary judgment in favor of the defendants on the Non-Trial Plaintiffs' claims and remand for further proceedings, excepting the grant of summary judgment to defendants on the claims of the Non-Trial Plaintiffs represented by Shawn A. Bozarth, Esq., and Peter J. Neeson, Esq. See n. 181, supra. We will dismiss the appeals of those

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exceedingly difficult, intricate and complex litigation. She has done so in a manner that reflects patience, fairness, and a desire to let both sides be heard. For example, as noted earlier, she allowed plaintiffs to present a portion of Wing's testimony even though she believed it to be marginally admissible. She allowed reports to be submitted after her January 5, 1996 order even though that order warned counsel about ignoring deadlines.

This is not to say that this litigation has proceeded without shortened tempers, strained patience, heated exchanges, or legal error. Such is often encountered in litigation of this magnitude, importance and complexity. However, it appears to us that Judge Rambo has continued to preside over this litigation as fairly as is humanly possible, and in a manner that is remarkably free of legal error.

particular appellants for failure to file briefs. See Matute v. Procoast Nav. Ltd., 928 F.2d 627, 630-31 & n. 1 (3d Cir.), cert. denied, 502 U.S. 919, 112 S.Ct. 329, 116 L.Ed.2d 270 (1991), overruled on other grounds, Neely v. Club Med Management Services, Inc., 63 F.3d 166, 177-78 (3d Cir.1995). Finally, we will deny the request for reassignment.

APPENDIX B — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT DATED AND FILED JANUARY 4, 2000, AMENDING OPINION DATED AND FILED NOVEMBER 2, 1999

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

Nos. 96-7623/7624/7625

IN RE: TMI LITIGATION

LORI DOLAN; JOSEPH GAUGHAN; RONALD WARD; ESTATE OF PEARL HICKERNELL; KENNETH PUTT; ESTATE OF ETHELDA HILT; PAULA OBERCASH; JOLENE PETERSON; ESTATE OF GARY VILLELLA; ESTATE OF LEO BEAM,

Appellants No. 96-7623

IN RE: TMI LITIGATION

ALL PLAINTIFFS EXCEPT LORI DOLAN, JOSEPH GAUGHAN, RONALD WARD, ESTATE OF PEARL HICKERNELL, KENNETH PUTT, ESTATE OF ETHELDA HILT, PAULA OBERCASH, JOLENE PETERSON, ESTATE OF GARY VILLELLA AND ESTATE OF LEO BEAM,

Appellants No. 96-7624

Appendix B

IN RE: TMI LITIGATION

ALL PLAINTIFFS; ARNOLD LEVIN; LAURENCE BERMAN; LEE SWARTZ,

Appellants No. 96-7625

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF PENNSYLVANIA
(Civil No. 88-cv-10452)
(District Judge: Honorable Sylvia H. Rambo)

Before: GREENBERG and McKEE, *Circuit Judges*, and GREENAWAY, *District Judge**

(Opinion filed: November 2, 1999)

ORDER AMENDING OPINION

IT IS HEREBY ORDERED, that the Slip Opinion filed in this case on November 2, 1999, be amended as follows:

> On page 85 [page 114a of the Join Appendix filed herein], at the conclusion of the sentence, "With the parameters of our inquiry in mind, the teachings of *Daubert* and the aforementioned scientific principles as guideposts, we can now proceed to apply the yardstick of *Daubert* to the

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* The Honorable Joseph A. Greenaway, Jr., United States District Judge for the District of New Jersey, sitting by designation.

expert opinions at issue here and determine if they were properly excluded under the Rules of Evidence." insert as footnote number 93 the following text:

Our recent holding in *Padillas v. Stork-Gamco, Inc.*, 186 F.3d 412 (3d Cir. 1999), does not assist our inquiry. In *Padillas*, the defendant moved for summary judgment, arguing that the plaintiff's expert's report did not meet *Daubert* standards for admissibility. The District Court excluded the expert's report and granted summary judgment to the defendant without an *in limine* hearing. We reversed and remanded for an *in limine* hearing.

We were concerned with the process the District Court must generally use in exercising its gatekeeping role under *Daubert*. We noted that "[w]e have long stressed the importance of *in limine* hearings under Rule 104(a) in making the reliability determination required under Rule 702 and *Daubert*." *Id.* at 417 (quoting *United States v. Downing*, 753 F.2d 1224, 1241 (3d Cir. 1985); *In Re Paoli Railroad Yard PCB Litigation*, 916 F.2d 829, 854 (3d Cir. 1990) ("Paoli I"); and *Hines v. Consolidated Rail Corp.*, 926 F.2d 262, 272 (3d Cir. 1991)), especially when a *Daubert* challenge is made in the context of a summary judgment motion or where summary judgment will inevitably be granted if the proffered evidence is excluded. Thus, we expressed our belief that

an *in limine* hearing is important, even in the absence of a request for such a hearing by the proponent of the expert testimony, because of the District Court's "independent responsibility for the proper management of complex litigation," and because the plaintiff "need[s] an opportunity to be heard" on the critical issues of scientific reliability and validity. *Id.* When afforded such an "opportunity to be heard," a plaintiff has a chance to have his or her expert demonstrate and explain the "good grounds" upon which the expert evidence rests. *Id.* at 418. Moreover, an opportunity to demonstrate the expert's "good grounds" is particularly important when the court's ruling on admissibility turns, in large part, upon "the factual dimensions of the expert evidence." *Id.* We did not intend to suggest that an *in limine* hearing is always required for *Daubert* gatekeeping. Rather, we held that "when the ruling on admissibility turns on factual issues, . . . , at least in the summary judgment context, failure to hold [an *in limine*] hearing may be an abuse of discretion." *Id.* at 418.

Padillas does not apply to our current inquiry because here, the District Court held extensive *in limine* hearings — lasting almost five full weeks — during which the trial plaintiffs were certainly given the "opportunity to be heard" in defense of their experts' submissions. *Padillas* certainly does not establish that a District Court must provide a plaintiff with an open-ended and

never-ending opportunity to meet a *Daubert* challenge until plaintiff "gets it right" and it certainly does not establish that a plaintiff must be given the opportunity to meet a *Daubert* challenge with an expert's submission that is based on a new methodology completely different from the one the expert originally engaged in.

Further, increase each footnote following added footnote 93 by one numeral.

IT IS SO ORDERED.

BY THE COURT,

/s/ Theodore A. McKee
Circuit Judge

DATED: January 4, 2000

A True Copy:
Teste:

Clerk of the United States Court of Appeals for the Third Circuit

APPENDIX C — MEMORANDUM AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF PENNSYLVANIA DATED AND FILED AUGUST 7, 1996

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

CIVIL ACTION NO. 1:CV-88-1452

IN RE TMI LITIGATION
CASES CONSOLIDATED II

This Document Relates to:
All Plaintiffs

MEMORANDUM

Before the court is the brief of attorneys Arnold Levin, Laurence Berman and Lee Swartz ("counsel") to show cause why monetary sanctions should not be imposed for violations of the mandatory disclosure provisions of Federal Rule of Civil Procedure 26(a) and disregard of court orders issued pursuant to Rule 26(f). Although the court did not request Defendants to file a responsive brief, they did so without leave of court. Counsel, likewise, have filed a reply. Prior to counsels' notification to the court that they would reply to Defendants' responsive brief, the court intended to strike Defendants' filing. However, as counsel have had the opportunity to respond, and in order to have a complete record of this issue on appeal, the court will strike neither Defendants' response nor counsels' reply. The rule to show cause is now ripe for disposition.

Appendix C

In its memorandum of law dated April 2, 1996, the court provided a lengthy discussion of the law governing its ultimate decision on the issue of sanctions, and the facts of the instant case which the court believed to support the imposition of sanctions. *See In re TMI Litigation Cases Consol. II*, 922 F. Supp. 997, 1000-08 (M.D. Pa. 1996). The course of conduct at issue is as follows:

> Pursuant to an order dated May 13, 1994, Plaintiffs were to file the expert reports of James Gunckel, Richard Webb and Ignaz Vergeiner not later than August 1, 1994. This order also directed that expert reports on medical causation were to be filed not later than September 1, 1994 and that expert reports on punitive damages were to be filed not later than October 1, 1994. On August 1, 1994, Plaintiffs filed the 6/94 report of Ignaz Vergeiner ("TMI Treatise 1"), and the 5/26/94 and 8/1/94 affidavits of Douglas Crawford- Brown. On August 4, 1994, Plaintiffs filed the 8/1/94 preliminary report of Richard Webb entitled "A Preview Short Synopsis." Thus, the report of James Gunckel was not timely filed on August 1, and the August 4 filing of the Webb "Preview" was both untimely and in contravention of Rule 26(a)(2) of the Federal Rules of Civil Procedure ("The report shall contain a *complete* statement of *all* opinions to be expressed and the basis and reasons therefor. . ."). The court was remiss in not striking these filings immediately and, in temporarily overlooking these rule violations, the court may have unwittingly encouraged Plaintiffs'

improper conduct. The record reflects that these 1994 filings were only the first in a long stream of improper and untimely filings.

On September 15, 1994, one and one-half months after the filing deadline, Plaintiffs filed the 7/6/94 Affidavit of Vladimir Shevchenko. On November 3, 1994, the court entered the final joint case management schedule. This schedule extended the deadline for Plaintiffs' filing of dose and medical causation expert reports to March 1, 1995.[1] On March 1, Plaintiffs filed the expert "reports"[2] of the following experts: Armentrout, Crawford-Brown, Gunckel, Hinrichesen, Lochbaum, Shevchenko, Vergeiner, Webb, Wing, Fajardo, Winters, Zakrzewski. On March 14, without leave of court, Plaintiffs supplemented their March 1 filing with the reports of Shevchenko, Tascaev, Kozubov, Popov, Portman, Tarasenko, and Snigiryova. On March 15, again without leave of court, Plaintiffs supplemented

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1. The court notes that insofar as this order has retroactive application it cures the timeliness defects in Plaintiffs prior filings. (Footnotes 1-4 in the instant opinion appear in the original opinion at *In re TMI*, 922 F. Supp. at 1002-03 n. 4-7.)

2. In large part, these filings are not "reports" in the traditional sense of the word. For many of Plaintiffs' experts, a "report" consists of a compilation of affidavits updated over time. *See, e.g.*, Report of Douglas Crawford-Brown (2/27/95 Aff.; 8/1/94 Aff.; 6/10/94; Aff.; 5/26/94 Aff.); Report of Steven Wing (2/25/95 Aff.; 2/23/95 Aff.; 1/12/95 Aff.; 10/31/94 Aff.; 6/13/94 Aff.; 1/94 Aff.; 3/16/93 Aff.).

their March 1 filing with the report of Bruce Molholt. Finally, on March 29, without leave of court, Plaintiffs filed a third supplement to the March 1 filing adding to the reports of Shevchenko and Zakrzewski. Thus, as of April 1995, Plaintiffs had late-filed a significant portion of their expert reports on dose and medical causation.

In February 1995, the court issued a preliminary memorandum of law related to Defendants' motion *in limine* to exclude Dr. Molholt's 4/8/93 report, and ordered limited additional briefing with respect to certain of the *Paoli II* factors.[3] *In re TMI*, Mem. Op. at 22 (M.D. Pa. February 14, 1995) ("[T]he court has invited the parties to respond concisely to the issues raised . . . this is not an invitation to deluge the court with paper. Clear, concise, relevant information will assist the court in reaching a just resolution; likewise, the submission of frivolous or irrelevant information will be frowned upon.") As exhibits to their court-ordered filing, Plaintiffs submitted several new expert reports (5/1/95 Molholt; 4/24/95 Kerman; 5/2/95 Kerman; 2/27/95 Crawford-Brown). In September 1995, Plaintiffs, again without leave of court, untimely

3. The court directed the additional briefing to clarify the parties' positions and to assist the court in reaching a final determination on the admissibility of the proffered testimony of Dr. Molholt.

filed the reports of Theodore Sterling and Ronald Kerman.

The next battery of Plaintiffs' expert reports were filed as exhibits to their opposition to Defendants' motion *in limine* to exclude Plaintiffs' dose experts. On October 25, Plaintiffs filed as exhibits the updated reports of the following experts: Vergeiner (two separate affidavits dated 10/18/95), Armentrout (10/10/95 Aff.; 10/22/95 Aff.), Gunckel (8/23/95 Aff.), Shevchenko (10/6/95 Aff.), Wing (10/19/95 Aff.), Crawford-Brown (10/20/95 Aff.), Molholt (9/8/95 Aff.; 9/14/95 Aff.). On October 31, with leave of the court,[4] Plaintiffs' supplemented the

4. Through a Memorandum and Order dated October 19, 1995, the court re-opened discovery from October 20 to October 30 for the purpose of granting Plaintiffs access to original plant data stored at the Emaus Street repository. The court granted Plaintiffs motion to compel despite the fact that "[a]fter sitting on their right to access these materials for nearly one decade, Plaintiffs now, one week before their brief on the *in limine* issues is due and after the formal close of discovery, request that Defendants be compelled to produce the aforementioned documents merely because it would not be inordinately difficult for Defendants to do so." 10/19/95 Order at 3. Plaintiffs offered the court no explanation as to why they had failed to view this material during the formal discovery period. *Id.*

Pursuant to its granting the motion to compel, the court allowed Plaintiffs "to supplement their brief in opposition to Defendants' motion *in limine*." The court allowed Plaintiffs to supplement the record to the extent that something in the original strip chart data proved helpful to their case. Plaintiffs were not granted permission to supplement the record with anything beyond the scope of the "new" original plant data.

record with the following affidavits/new reports: Armentrout (9/20/95 Aff.; 5/11/95 Aff.), Blanch (10/31/95 Aff.), Kerman (10/30/95 Aff.), King (10/30/95 Aff.), Reyblatt (10/31/95 Aff.), Shevchenko (10/6/95 Aff.), Kozubov (9/12/95 Aff.), Smirennyi (10/30/95 Aff.), Wing (10/27/95 Aff.). On January 16, 1996, as exhibits to a brief in opposition to Defendants' motion to compel, Plaintiffs filed the following supplemental affidavits: Crawford-Brown, Ornstein, Purcell, Reyblatt. Finally, during February 1996, Plaintiffs filed the following supplemental affidavits without leave of court: Wing (10/19/95 Aff.; 1/26/96 Aff.; 1/31/96 Aff.; 2/7/96 Aff.), Kozubov (1/30/96 Aff.), Armentrout (2/1/96 Aff.), Milhollin (5/5/96 Aff.), Griffin (1/30/96 Aff.), King (2/16/96 Aff.).

In re TMI, 922 F. Supp. at 1001-03. As the court's reasoning is of record, there is no need to repeat it. *Id.* at 1003-08. Finding the imposition of sanctions to be warranted, the court directed counsel to show cause why sanctions should not be imposed. The court will now address the merits of the arguments raised by counsel in opposition to the imposition of sanctions.

In the April 2 memorandum, the court indicated that counsel had failed to offer any substantial justification for their Rule 26 violations.[5] Counsel, in both their initial filing

5. In their reply brief, counsel find fault with the court's conclusion that they failed to offer substantial justification for the (Cont'd)

and their reply brief, respond to the court's observation by implying that Defendants and/or the court were obligated to place counsel on notice of their discovery violations. Specifically, counsel contend that "[t]he lack of any motions or court action gave plaintiffs' counsel reason to believe that compliance with the rules of discovery was not an issue." (Resp. of Pls.' Counsel to Court's Order to Show Cause at 28.) Plaintiffs proffer this explanation as their "substantial justification" for failing to comply with Rule 26. Plaintiffs have misconstrued the plain language of Rule 26. Rule 26(a)(2)(B) imposes an affirmative obligation on the party proffering the expert testimony (here Plaintiffs) to fully disclose a *complete* statement of the expert's opinion and the "basis and reasons therefor". Rule 37 provides for *self-executing* discovery sanctions in the event that a party fails to comply with the mandatory disclosure requirements. It is axiomatic that a Defendant is not required to file a motion to compel where a plaintiff is under an affirmative duty to supply expert discovery materials, and where sanctions relating to an abdication of that duty are self-executing.

(Cont'd)

Rule 26 violations. Specifically, counsel note that prior to the court's *sua sponte* imposition of sanctions there was no motions practice on the issue. Counsel are correct that insofar as Defendants did not file a motion seeking to impose sanctions, there has been no direct briefing of the issue. However, it is incorrect to suggest that counsel were not previously given the opportunity to justify their conduct to the court. The issue of Plaintiffs' late and incomplete expert filings was raised and discussed throughout the *in limine* process in Defendants' motions *in limine*, and was the subject of discussion at the pre-hearing conference, during an in chambers conference, during telephone conferences and at the hearings themselves. Plaintiffs' counsel have had ample opportunity to explain and justify their conduct to the court.

Similarly, the court finds counsels' insinuation that the court was under some affirmative obligation to advise them of their discovery violations as they occurred untenable. The notion that a court is obligated to do anything more than issue a scheduling order and expect the parties to abide by that order is implausible. Were the court responsible for "policing" the filings of all litigants comprising the hundreds of cases on its docket, it would be impossible for the court to conduct its real business — disposing of the cases before it. As counsel assisted in drafting the joint case management schedule which contained the deadlines for their expert submissions, the court finds counsels' arguments regarding lack of notice of deadlines or the need to conform therewith to be particularly unpersuasive.

Next, counsel argue that there was a substantial legal basis, and thus a substantial justification, for the manner in which they handled their expert disclosure and filing. Counsel rely heavily on Rule 26(e)(1) in support of this argument. It is asserted that "[e]ach of plaintiffs' supplemental expert submissions complied with the letter and spirit of Rule 26(e)." The court cannot agree. Rule 26(e) places a duty upon a party to timely supplement prior disclosures to the extent that there is a need to correct or make more complete a prior disclosure. Fed. R. Civ. P. 26(e) advisory committee's note. The Rule does not give a party free reign to provide incomplete or draft "preliminary" mandatory disclosures, and then follow with "supplemental" disclosures that make the "preliminary" disclosure "final." *See Sierra Club, Lone Star Chapter v. Cedar Point Oil Co., Inc.*, 73 F.3d 546, 571 (5th Cir. 1996) ("The purpose of rebuttal and supplementary disclosures is just that — to rebut

and to supplement. These disclosures are not intended to provide an extension of the deadline by which a party must deliver the lion's share of its expert information."). In fact, it was a goal of the 1993 amendment to deter this type of piecemeal discovery practice and streamline disclosure. *See* Fed. R. Civ. P. 26(a) advisory committee's notes. Accordingly, to the extent that Plaintiffs' supplemental filings proffered entirely new methodologies, tests or analyses, or for the first time revealed steps of a methodology that should have been included in the "complete" mandatory disclosure, the court found the evidence to be inadmissible.[6] That counsel misinterpreted the language of, advisory notes to, and existing case law regarding Rule 26(a) and 26(e) is not substantial justification for violating the Rules.[7]

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6. Nevertheless, finding that wholesale exclusion of all such evidence would be unfairly detrimental to Plaintiffs' case, the court found the more appropriate sanction to be exclusion of certain of the evidence combined with the imposition of monetary fines on Plaintiffs' counsel. *Cf. Estate of Spear v. C.I.R.*, 41 F.3d 103, 112 (3d Cir. 1994) ("When a party does not provide information to another party to which that party is entitled, a court is certainly permitted to 'even out' the proceedings by shifting the burden of proof [by excluding evidence or deeming facts admitted,] in a fair way even in the absence of bad faith.") Moreover, the court notes that to the extent that Plaintiffs' expert submissions were truly rebuttal or supplemental in nature, they were not subject to any challenge by Defendants or admissibility determination by this court.

7. As explained in the April 2 memorandum, due to the complexity and novelty of the evidentiary issues involved in this case, timely filing of expert materials was of heightened importance. *In re TMI*, 922 F. Supp. at 1005-06. As the court reads Rule 26, *Daubert* and *Paoli II*, to properly conduct its *Daubert* inquiry, the

(Cont'd)

Appendix C

Finally, counsel argue that even if the court finds that they lacked substantial justification for their untimely and incomplete expert filings, the court cannot find that Defendants were harmed by the filings or that counsel acted in bad faith. In the April 2 memorandum, the court described the harm occasioned as a result of counsels' Rule 26 violations. *See In re TMI*, 922 F. Supp. at 1004-07. Nothing in counsels' show cause filings moves this court to alter its initial findings on this issue. As to bad faith, the Seventh Circuit, discussing violations of a protective order, defined the phrase as "conduct which is either intentional or in reckless disregard of a party's obligations to comply with a court order." *Marrocco v. General Motors Corp.*, 966 F.2d 224, 224 (7th Cir. 1992) In the instant manner, counsels' conduct is better characterized as reckless than intentional. On a number of occasions following the November 1994 adoption of the parties' joint case management plan, counsel were reminded of the court's strong feelings regarding adherence to case management and scheduling orders. *See, e.g.*, 11/3/94 Order ("All deadlines stated in the schedule are binding deadlines. No changes in deadlines, nor extensions of time, will be granted absent extreme and compelling circumstances."); 4/28/95 Order (denying parties' joint stipulation for a two month extension of all deadlines, reminding parties that they "were forewarned that they would be held to the stipulated case management schedule [dated 11/3/94]," and again stressing that "the deadlines set by the

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(Cont'd)
court needed access to *complete* statements of the methodologies upon which challenged expert testimony was based, and needed access to the materials relied upon by the experts which supported the methodologies.

November . . . joint case management schedule are binding"); 5/5/95 Order (granting extension of time as to the filing of court-ordered supplemental *briefing* regarding Dr. Molholt and noting that the court would "not change the June 15, 1995 deadline for Defendants' submission of expert reports on dose and medical causation"); 5/8/95 Order (issuing the court's "non- negotiable" revised case management schedule placing the case on the June 1996 trial list); 5/15/95 Order (denying joint request to revise the 5/8/95 case management order and noting that the May 8 order "expressly stated the court's view that the schedule is 'non-negotiable' . . . . [and that the court] finds it disconcerting that the parties chose to ignore the gravamen of the scheduling order"); *see also* 5/19/95 Order (noting the parties' representation to the court that they favored the court's case management schedule and were intent upon seeing the case go to trial in June of 1996); 10/19/95 Order (discussing Plaintiffs' failure to view documents in the Emaus Street repository during the seven years that the repository was open and noting that "Plaintiffs offer no explanation as to why they failed to visit the document repository before April of 1995"); 11/9/95 Order (excluding certain of Plaintiffs' untimely filed expert reports). The court finds that counsels' handling of expert disclosure, in the face of these orders and numerous verbal admonishments by the court, exhibits a reckless disregard for the mandatory disclosure requirements of Rule 26(a) and the scheduling and case management orders issued by this court pursuant to Rule 26(f).[8]

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8. Counsel also contend that their due process rights have been violated because the court has refused to allow them to be heard on the show cause issue. The court reads counsels' brief to mean "heard"

(Cont'd)

Appendix C

Based upon the foregoing discussion, and the discussion contained in the court's April 2 memorandum of law, the court finds that counsel have failed to show cause why sanctions should not be imposed. Accordingly, the court will impose sanctions, in the amount of five hundred dollars per attorney, upon counsel pursuant to Rule 37(b) and (c) of the Federal Rules of Civil Procedure and pursuant to this court's inherent power to sanction attorneys for improper conduct. An appropriate order will issue.

(Cont'd)
in the literal sense of the word, as the court indicated that it would not hear oral argument or conduct a telephone conference on the show cause issue. In support of their position, counsel cite to *Societe Internationale Pour Participations Industriales Et Commerciales v. Rogers*, 357 U.S. 197, 209 (1958). Counsel contend that "while *Societe Internationale* spoke of the due process limitations imposed on the dismissal of a case as a discovery sanction, there is no question that the same due process limitations apply whenever a court exercises its power, under Rule 37 or another source, to impose a sanction, related to purported discovery violations." (Resp. of Pls.' Counsel to Court's Order to Show Cause at 37-38.) The court agrees with counsel that it must respect counsels' due process rights and afford them the opportunity to respond on the record before imposing sanctions. In express recognition of counsels' due process rights, the court permitted extensive responsive briefing on the sanctions issue. *See In re TMI*, 922 F. Supp. at 1008 (noting the importance of complying with the mandates of due process). The facts of the instant matter are sufficiently distinguishable from those of *Societe Internationale* for the court to conclude that counsels' due process rights were not violated, and to find they were given adequate opportunity to be heard through seventy-two (72) pages of briefing. As such, the court continues to believe that it is not constitutionally bound to hear oral arguments on the sanctions issue, and that such arguments would be of little utility to the court as such extensive briefing is of record.

Appendix C

s/ Sylvia H. Rambo
SYLVIA H. RAMBO, Chief Judge
Middle District of Pennsylvania

Dated: August 7, 1996

Appendix C

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

CIVIL ACTION NO. 1:CV-88-1452

IN RE TMI LITIGATION
CASES CONSOLIDATED II

This Document Relates to:
All Plaintiffs

ORDER

In accordance with the accompanying memorandum of law, **IT IS HEREBY ORDERED THAT**:

1) Sanctions are imposed on attorneys Arnold Levin, Laurence Berman and Lee Swartz in the amount of $500.00 per attorney;

2) Counsel shall remit payment to the Clerk of Court, United States District Court for the Middle District of Pennsylvania, on or before August 17, 1996;

3) As the court has already devoted two opinions to the merits of the sanctions issue, and as the discovery issues underlying the imposition of sanctions have been the subject of many discussions between the court and counsel for both parties, the court finds that any motion to reconsider would be frivolous and without merit. Consequently, the court will not entertain a motion for reconsideration of this order.

Appendix C

s/ Sylvia H. Rambo
SYLVIA H. RAMBO, Chief Judge
Middle District of Pennsylvania

Dated: August 7, 1996

APPENDIX D — MEMORANDUM OF THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF PENNSYLVANIA DATED JUNE 7, 1996, AS CORRECTED JUNE 12, 1996

In re TMI LITIGATION CONSOLIDATED PROCEEDINGS.
This Document Relates to All Plaintiffs.

Civil Action No. 1:CV-88-1452.

United States District Court,
M.D. Pennsylvania.

June 7, 1996.

As Corrected June 12, 1996.

* * *

Appendix D

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Appendix D

MEMORANDUM

RAMBO, Chief Judge.

On March 28, 1979, a nuclear incident occurred at the Unit 2 reactor of the Three Mile Island nuclear power facility in Dauphin County, Pennsylvania. Among other things, the incident spawned the instant litigation[1] which has been pending on the court's docket for one decade longer than all but one case on the court's docket.[2] Due in significant part to the tremendous amount of time and effort expended by the parties and the court over the past year, ten test cases were finally scheduled for trial beginning in June.[3] In January and April of this year, the court issued a series of Daubert rulings excluding the bulk of Plaintiffs' expert scientific testimony as scientifically unreliable. In re TMI Cases Consol. II, 166 F.R.D. 8 (M.D.Pa.1996) (granting in part Defendants' motions in limine to exclude Plaintiffs' medical causation experts); id. 922 F.Supp. 1038 (M.D.Pa.1996) (same); id. 922 F.Supp. 997 (M.D.Pa.1996) (granting in part Defendants' motions in limine to exclude Plaintiffs' dose

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1. The court notes that a plethora of government investigations, privately funded studies, and the ignition of a national dialogue as to the safety and utility of nuclear power are among the other important acts spawned by the TMI incident.

2. Holloway v. Cohen, Civil No. 1:CV-85-1338, has been stayed for ten years awaiting the conclusion of state court proceedings.

3. On May 30, 1996, the court issued an order removing the cases from the June trial list.

and medical causation experts); id. 910 F.Supp. 200 (M.D.Pa.1996) (granting in part Defendants' motion in limine to exclude Plaintiffs' dose experts); id. 911 F.Supp. 775 (M.D.Pa.1996) (same). Defendants now move for summary judgment.[4] The parties have briefed the issues and Defendants' motion is ripe for disposition. Before reaching the merits of Defendants' motion, however, the court must first address the subsidiary yet important issue of to whom the court's summary judgment ruling will apply. Defendants argue that based upon the way in which they have framed their motion, any ruling by the court should be binding upon all Plaintiffs. Conversely, Plaintiffs argue that the ruling should bind only the test Plaintiffs.

To resolve this issue, the court refers back to its memorandum and accompanying order dated June 15, 1993. Through that order the court adopted Plaintiffs' proposed case management plan and "test plaintiff" approach, and rejected Defendants' case management plan and "track litigation" approach. In its discussion of Plaintiffs' proposed plan, the court noted the following:

> Plaintiffs claim that this initial trial would provide a basis for the parties realistically to evaluate their

---

4. This is the second time that Defendants have moved for summary judgment. The first motion, related to the issue of duty, was denied by this court on February 18, 1994. The United States Court of Appeals for the Third Circuit, affirming in part this court's ruling, found that Defendants violated the duty of care owed. In re TMI Cases Consol. II, 67 F.3d 1103, 1118 (3d Cir.1995). Accordingly, the only remaining legal and factual issues in the case relate to causation and damages. See id. at 1119.

> respective cases and promote settlement of this action. Defendants contend that "the 'test-case' approach does not portend to resolve anything except the test cases selected." Therefore, Defendants assert that the initial twelve-Plaintiff[5] trial would not promote settlement or be otherwise useful.

In re TMI Cases Consolidated II, No. 1:CV-88-1452, mem. op. at 26 (M.D.Pa. June 15, 1993) (footnote added). Defendants now argue that "[t]he fact that the court has scheduled trial for ten 'test case' plaintiffs does not mean that all the pretrial consolidated proceedings, designated with the caption 'All Plaintiffs,'[6] should . . . be regarded

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5. Initially, twelve test cases were scheduled for trial, six test parties selected by Plaintiffs and six selected by Defendants. One of Defendants' selections subsequently withdrew from the test group. Accordingly, the court permitted Defendants to chose one of the parties originally selected by Plaintiffs to be dismissed from the "test Plaintiff action."

6. On July 9, 1992, the court approved a stipulation which provided for the use of different captions on documents applying to all plaintiffs as opposed to those applying merely to certain individual plaintiffs. Specifically, the stipulation noted as follows:

> Hereafter, pleadings dealing with issues common to all plaintiffs, or a legal issue potentially applicable to all plaintiffs shall be captioned "In Re TMI Consolidated Proceedings" and shall bear the additional legend, "This Document Relates To: All Plaintiffs. . . ."
>
> A pleading dealing with issues applicable to one or more identified plaintiffs shall be captioned "In Re TMI

(Cont'd)

retrospectively as applicable only to those 'test case' plaintiffs." (Defs.' Reply Mem. at 26.) Indeed, the purpose of consolidating an action pursuant to Federal Rule of Civil Procedure 42(a) is to streamline and economize pretrial proceedings so as to avoid duplication of effort, and to prevent conflicting outcomes in cases involving similar legal and factual issues. See In re Prudential Securities Incorporated Ltd. Partnerships Litigation, 158 F.R.D. 562, 571 (S.D.N.Y.1994); Bank of Montreal v. Eagle Associates, 117 F.R.D. 530, 533 (S.D.N.Y.1987).

The court finds that resolution of the issue before it turns on the grounds upon which the court ultimately grants or denies summary judgment. Defendants are correct that to the extent the ruling turns on broad evidentiary issues common to all Plaintiffs, the ruling will be binding upon all Plaintiffs. Likewise, Plaintiffs are correct that insofar as a ruling is based upon a more narrow, Plaintiff-specific inquiry, the ruling will apply only to certain Plaintiffs. The court's reading of documents related to the June 15, 1993 order, in conjunction with subsequent case management orders and

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(Cont'd)

> Consolidated Proceedings" and shall bear the additional legend, "This Document Relates To:" and shall include lead counsel's name, number of plaintiffs represented by lead counsel and number of plaintiffs for whom the pleading refers. An additional page bearing the legend, "This Document Relates to the Following Plaintiffs:" shall be attached and each such individual plaintiff shall be named.

7/8/92 Amended Stipulation at 3 (approved in 7/9/92 order).

evidentiary rulings, indicates that discovery and evidentiary matters were to proceed on an "All Plaintiffs" basis. A contrary intention or result would obviate all benefits of having consolidated the many separate actions. Each Plaintiff's case depends upon expert testimony to prove both exposure and medical causation. Expert discovery is complete, and all expert reports have been filed. Thus, to the extent that the expert testimony of record fails to meet the test Plaintiffs' evidentiary burden at this stage of the litigation, it will fail to meet the same burden as to every Plaintiff. It would be an exercise in futility and a waste of valuable resources to allow the many separate actions consolidated under this caption to proceed if it were clear that the cases could not withstand a motion for summary judgment. Under such circumstances, the court's summary judgment ruling would be applicable to all Plaintiffs.[7]

In accordance with the discussion that follows, the court will grant Defendants' motion for summary judgment on the ground that Plaintiffs have failed to present evidence sufficient to create a material factual dispute on the issue of dose, and therefore, have failed to state their prima facie

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7. Plaintiffs argue that their Seventh Amendment right to a jury trial would be abrogated should the court make the instant ruling binding upon all Plaintiffs. The court cannot agree. Insofar as the evidence before the court is insufficient to either create a material factual dispute or carry Plaintiffs' burden at trial, Plaintiffs do not, as a matter of law, have any right to a jury trial. City of Chanute, Kansas v. Williams Natural Gas Co., 955 F.2d 641, 656 (10th Cir.1992) ("[S]ummary judgment, applied properly, does not violate the Seventh Amendment.") (citing Fidelity & Deposit Co. v. United States ex rel. Smoot, 187 U.S. 315, 319-21, 23 S.Ct. 120, 121-22, 47 L.Ed. 194, 47 L.Ed. 194 (1902)).

case. Because the court finds the quantum of Plaintiffs' expert evidence on the issue of dose to be insufficient, and because no Plaintiff will be able to state a prima facie case without adequate dose evidence, the instant ruling is binding upon all Plaintiffs.

I. Background

A. Procedural History

The consolidated claims in this case were initially filed shortly after the TMI incident in the state and federal courts of Pennsylvania, New Jersey and Mississippi. Since the initial filings, these cases have traveled to and from the Supreme Court, the Third Circuit Court of Appeals, and several district courts on numerous occasions. Moreover, jurisdictional questions related to these actions prompted Congress to amend the Price Anderson Act to ensure federal court jurisdiction, see S.Rep. 100-218, 100th Cong.2d Sess., 1988 U.S.C.C.A.N. 1424, 1476, 1488 (noting that the TMI litigation provided the impetus for amending the federal jurisdiction section of the Act). A brief review of the consolidated claims' meandering journey to this court is warranted.

In the mid and late 1980s, based upon the assertion that Plaintiffs' claims arose under the Price Anderson Act, Pub.L. No. 85-256, 71 Stat. 576 (codified as amended in various sections of title 42 of the United States Code), Defendants removed Plaintiffs' state court actions to federal courts in Pennsylvania and Mississippi. On appeal, the Third Circuit found that because the Nuclear Regulatory Commission

("NRC") had determined that the TMI incident did not constitute an "extraordinary nuclear occurrence,"[8] the TMI

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8. Pursuant to 10 C.F.R. §§ 140.84 and 140.85, the NRC may determine that there has been an Extraordinary Nuclear Occurrence ("ENO") where two sets of criteria are met. "Criterion I relates to whether there has been a substantial discharge or dispersal of radioactive material off the site of the reactor, or that there has been a substantial level of radiation offsite." NUREG-0637, Report to the Nuclear Regulatory Commission from the Staff Panel on the Commission's Determination of an Extraordinary Nuclear Occurrence (ENO) at 8 (NRC 1980). If Criterion I is met, the Criterion II factors are evaluated. Criterion II is met if any of the following findings are made:

> (1) The event has resulted in the death or hospitalization, within 30 days of the event, of five or more people located offsite showing objective clinical evidence of physical injury from exposure to the radioactive, toxic, explosive or other hazardous properties of the reactor's source, special nuclear, or byproduct material; or
>
> (2) $2,500,000 or more damage offsite has been or will probably be sustained by any one person, or $5 million or more of such damage in total has been or will probably be sustained, as the result of such event; or
>
> (3) The Commission finds that $5,000 or more of damage offsite has been or will probably be sustained by each of 50 or more persons, provided that $1 million or more of such damage in total has been or will probably be sustained, as the result of such event.

Id. at 11.

claims did not arise under the provisions of the Price-Anderson Act. Stibitz v. General Pub. Utils. Corp., 746 F.2d 993 (3d Cir.1984), cert. denied, 469 U.S. 1214, 105 S.Ct. 1187, 84 L.Ed.2d 334 (1985); Kiick v. Metropolitan Edison Co., 784 F.2d 490 (3d Cir.1986). As such, the Third Circuit ruled that this court lacked jurisdiction to hear the actions. Stibitz, 746 F.2d at 997; Kiick, 784 F.2d at 494-95. Pursuant to that rulings, this court remanded those actions originally filed in state court, and transferred those actions originally filed in federal court, to the appropriate state courts.

Following this court's remand and transfer of cases to state courts, Congress amended the Price-Anderson Act. 42 U.S.C. § 2011 (Price-Anderson Amendments Act of 1988). The amendment retroactively provided a federal forum for all claims arising out of any nuclear incident, whether or not that incident was declared to be an "extraordinary nuclear occurrence." 42 U.S.C. § 2210(n)(2). Original jurisdiction was conferred upon district courts located where the incident occurred, and provision was made for the removal of any action previously filed or currently pending in state court. § 2210(n)(2). Subsequently, the constitutionality of the Act's federal forum provision was upheld in In re TMI Litigation Cases Consol. II, 940 F.2d 832 (3d Cir.1991), cert. denied, 503 U.S. 906, 112 S.Ct. 1262, 117 L.Ed.2d 491 (1992). Pursuant to § 2210(n)(2), all remaining claims were then consolidated in this court.

On January 26, 1993, Defendants moved for summary judgment on all pending personal injury claims on the element of duty of care. Defendants argued that to prove liability, Plaintiffs would need to demonstrate that

Defendants violated their duty of care by exposing each Plaintiff to radiation in excess of .5 rem. See infra at 840-841 (defining "rem"). On February 18, 1994, this court issued a memorandum and order denying Defendants' motion. The Third Circuit affirmed this court's ruling in part, holding that "the duty of care is measured by whether defendants released radiation in excess of the levels permitted by [10 C.F.R.] §§ 20.105 or 20.106, as measured at the boundary of the facility, not whether each plaintiff was exposed to those excessive radiation levels." In re TMI Litig. Cases Consol. II, 67 F.3d 1103, 1117-18 (3d Cir.1995), cert. denied, 516 U.S. 1154, 116 S.Ct. 1034, 134 L.Ed.2d 111 (1996).

In November of 1995, and in February and March of 1996, this court conducted extensive Daubert hearings related to Plaintiffs' dose and medical causation experts. In January and April of 1996, this court issued several memoranda of law and accompanying orders granting the majority of Defendants' motions in limine. As these opinions, hundreds of pages in aggregate length, detail the court's reasoning, the court will not restate that reasoning here. In brief, however, the court notes that despite finding the vast majority of Plaintiffs' experts to be well qualified, the court found many of their opinions to be based upon methodologies that were scientifically unreliable and upon data that a reasonable expert in the field would not rely upon. Accordingly, in the exercise of its "gatekeeping" function, the court found it necessary to exclude much of Plaintiffs' proffered expert testimony. On April 19, 1996, Defendants filed the instant motion for summary judgment on the issues of dose and medical causation.

Appendix D

B. Scientific Background[9]

To understand the framework through which the court must view the scientific evidence in this case, it is necessary to have a basic understanding of the concepts and principles used by scientists to evaluate the impact of radiation exposure in human beings. The court will first provide a brief overview of basic concepts of radiation. Next the court will review relevant dose-related terms and concepts including the concept of background radiation, and the processes of dose reconstruction and risk assessment. Finally, the court will explain the basic operation of a Babcox & Wilcox pressurized water nuclear reactor, and will discuss general meteorological concepts relevant to the movement and dispersion of radioactive plumes.

1. Basic Concepts of Radiation

Atoms are the smallest unit of an element, and are composed of three types of particles: protons, neutrons and electrons. They may be stable or unstable. Unstable atoms emit surplus energy from the nucleus in a process known as radioactive decay. The energy emitted through radioactive decay is radiation. See generally, Allen v. United States, 588 F.Supp. 247, 260-87 (D.Utah 1984) (providing exhaustive discussion of basic principles of radiation and nuclear physics).

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9. In this section the court will present an overview of relevant scientific principles. The court will elaborate upon principles introduced here, to the extent that it is necessary, when reaching the merits of Defendants' motion for summary judgment.

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> For the purposes of this lawsuit, there are three basic types of ionizing radiation. An alpha particle is composed of two neutrons and two protons. . . . A beta ray is a single electron. A gamma ray is a photon, or bundle of energy which contains some of the properties of both matter and light.

Johnston v. United States, 597 F.Supp. 374, 384 (D.Kan.1984) (emphasis added). Gamma radiation is short wave length electromagnetic radiation spontaneously emitted by a nucleus during certain radioactive decays. (7/12/95 Aff. of John Fraizer at ¶ 14.) It has a high penetrating ability and can pass through the human body. In the instant action, Plaintiffs allege gamma ray exposure from xenon, radioactive iodine, and to a lesser extent, krypton.

Scientists quantify radiation in the following manner:

> [a]s radiation passes through air, it can be measured by counting the number of ionized particles it produces. The quantity 'exposure' has been historically defined as the number of electrical charges produced in a unit mass of air and measured in units of roentgens (R). . . . As radiation penetrates any material, its energy is absorbed and released by the constituent atoms. The absorbed energy per unit mass of material is termed the absorbed dose. The old unit of absorbed dose was the rad, defined as 100 ergs of energy per gram of material. . . . The effects of radiation on any material, including biological materials such as tissue, depend on the magnitude of the absorbed dose.

International Advisory Committee, "The International Chernobyl Project, Technical Report," at 20 (IAEA 1991) (hereinafter "Chernobyl Report"). The rad has been replaced by the international unit, the "gray" (Gy). One gray is equal to 100 rads. Another relevant dosimetric quantity is the "rem" (roentgen equivalent man). One rem is equal to one thousand milirems (mrems). The rem has been replaced by the international unit the "sievert" (Sv). One sievert equals 100 rems (100,000 mrems). Because much of the TMI literature predates the conversion to international units, the court will use rad and rem quantities to insure consistency with materials being cited.

2. Radiation Exposure and Dose

a. Background Radiation

All persons are exposed to radiation in their day to day existence. This radiation, known as "background radiation," comes from both natural and man-made sources. National Research Council, Committee on the Biological Effects of Ionizing Radiation, "Health Effects of Exposure to Low Levels of Ionizing Radiation" at 17 (1990) ("BIER V")[10];

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10. In O'Conner v. Commonwealth Edison Co., 807 F.Supp. 1376, 1382-83 n. 6 (C.D.Ill.1992), the court provided the following history of the BEIR reports:

> The National Academy of Sciences was established by President Abraham Lincoln in 1863 to provide the federal government with the advice of the best scientific minds in the country. It has a committee specifically

(Cont'd)

see also Chernobyl Report at 23-28. The BEIR V report states the following regarding annual exposure to background radiation in the United States:

> three of the six radiation sources, namely radiation from occupational activities, nuclear power production (the fuel cycle), and miscellaneous environmental sources (including nuclear weapons testing fallout), contributed negligibly to the average effective dose equivalent, i.e., less than 0.01 millisievert (mSv)/year (1 mrem/year).
>
> A total average annual effective dose equivalent of 3.6 mSv (360 mrem)/year to members of the U.S. population is contributed by the other three sources: naturally occurring radiation, medical uses of radiation, and radiation from consumer products. By far the largest contribution (82%) is made by natural sources, two thirds of which is caused by radon and its decay products.

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> dedicated to the health effects of ionizing radiation that issues periodic reports containing the most recent knowledge in this field. The most recent report is "Health Effects of Exposure to Low Levels of Ionizing Radiation: 1990 ("BEIR V"). . . ." The BEIR Reports are reliable authorities containing the distilled advice of scientists who have reviewed all of the eminent scientific literature in this field. It provides a yardstick by which a court can measure the validity of the various expert opinions offered by litigants.

Id.

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> Approximately equal contributions to the other one-third come from cosmic radiation, terrestrial radiation, and internally deposited radionuclides. The importance of environmental radon as the largest source of human exposure has only recently been recognized.
>
> The remaining 18% of the average annual effective dose equivalent consists of radiation from medical procedures (x-ray diagnosis, 11% and nuclear medicine, 4%) and from consumer products (3%). The contribution by medical procedures is smaller than previously estimated. For consumer products, the chief contributor is, again, radon in domestic water supplies, although building materials, mining, and agricultural products as well as coal burning also contribute. Smokers are additionally exposed to the natural radionuclide polonium-210 in tobacco, resulting in the irradiation of a small region of the bronchial epithelium to a relatively high dose . . . that may cause an increased risk of lung cancer.

BIER V at 18-19. The Johnston court also made the following interesting observations regarding natural background radiation:

> In order to make these units of measurement more meaningful, it is of interest to note what doses some common experiences yield. The earth in Florida gives a person living there a dose of approximately 23 mrem per year. If a person lives

> there for 64 years, he will receive a dose of 64 x 23 mrem = 1472 mrem from Florida dirt in a lifetime. This is equal to 1.472 rem. If another person lives in Colorado for 64 years, he will receive a dose of 64 x 90 mrem = 5760 mrem from Colorado dirt in a lifetime. This is equal to 5.76 rem. In 1970, approximately 129,000,000 Americans were exposed to x-rays for medical or dental purposes. . . . The average American by age 64 will receive about 6.5 rem of radiation from x-rays. Consequently, total [(lifetime)] doses of approximately 12 rem would be common for a [64 year old] Colorado resident who had normal exposure to dirt and x-rays.

Johnston, 597 F.Supp. at 389-90 (internal citations omitted) (citing BEIR III).[11] The effect of radiation exposure upon a human being is controlled by a number of variables. For example, the effects depend "not only on the absorbed dose, but also on the type and energy of the radiation causing the dose." Chernobyl Report at 20. In addition, the likelihood of observing effects will depend upon the tissue or organ irradiated and the degree of sensitivity of that tissue or organ to radiation. Id.

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11. Based upon the findings of the BEIR V report, the Johnston court's characterization of the effects of medical exposure may be overstated. BEIR V at 19 ("The contribution [to background exposure] by medical procedures is smaller than previously estimated."). Nevertheless, the Johnston court's illustrations of "typical" background exposure assist in placing the issue of exposure in the instant case in the appropriate context.

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b. Quantifying Dose/Dose Reconstruction

When considering the potential biological effects of exposure to ionizing radiation, it is necessary to consider the pathway through which the radiation entered the body.

> Following any release of radionuclides to atmosphere, people can be exposed via a number of different routes. As the radioactive cloud is dispersed and transported by the prevailing winds, people are initially exposed to radiation by two principal routes: external irradiation from material in the cloud and internal irradiation following inhalation of radioactive material in the air. Subsequently, the contents of the cloud are gradually depleted during its dispersion as radioactive materials are transferred to the ground and water bodies under dry weather conditions, with precipitation or in fog. People may then be exposed and may continue to be exposed by other routes, the three main ones being: external irradiation from the deposited material itself, the inhalation of any material resuspended into the atmosphere, and the transfer of material through the terrestrial and aquatic environment to food and water, which can give rise to internal irradiation.

Chernobyl Report at 31. Among other reasons, the pathway of exposure is important because it provides key information regarding potential exposure. For example, where exposure is internal, from ingestion of a radionuclide, exposure will

continue for the life of the radionuclide and will be highest in those organs most susceptible to exposure from the radionuclide ingested. See National Resource Council, Radiation Dose Reconstruction for Epidemiologic Uses 41-3 (1995); see infra at 843-844 (discussing authoritative materials upon which this handbook is based).

Two categories of effects may be observed following exposure to ionizing radiation: deterministic effects and stochastic effects. Deterministic effects of exposure to radiation arise from cell death. When a threshold number of cells within a given tissue or organ are killed, "there will be clinically observable pathological conditions such as a loss of tissue function or a consequential reaction as the body attempts to repair the damage. If the tissue is vital and is damaged sufficiently, the end result will be death." Annals of the ICRP, ICRP Publication 60, "1990 Recommendations of the International Commission on Radiological Protection" at 14 (1991) (hereinafter "ICRP 60").[12] Acute radiation

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12. According to the O'Conner court,

> The International Commission on Radiological Protection was founded in 1928, and since 1950 has been providing general guidance on the widespread use of radiation sources. The ICRP is comprised of eminent international scientists who review the world's literature on issues related to the health effects of radiation and periodically publish reports containing reliable consensus science statements in this field. These reports can be used by a court to evaluate expert's claims.

Id. at 1382 n. 4 (citation omitted).

syndrome,[13] for example, is a deterministic effect of radiation exposure. Stochastic effects occur when the irradiated cell

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13. The textbook Medical Effects of Ionizing Radiation provides the following discussion of acute radiation syndrome:

> The acute radiation syndrome is generally divided into 4 subgroups: (1) CNS syndrome, (2) cardiovascular syndrome, (3) gastrointestinal syndrome, and (4) hematopoietic syndrome. The acute CNS syndrome (group V) is generally reached only when the whole-body irradiation dose exceeds 50 Gy (5000 rad). The survival time is less than 48 hrs. . . . In general, symptoms are identified almost immediately and consist of disorientation, apathy, ataxia, prostration, and often tremor and convulsions. These seizures may result from minimal external stimuli. The cause of death is believed to be a function of several causes, including vascular damage, meningitis, myelitis, and encephalitis. Fluid infiltrates into the meninges, brain, and choroid plexus, causing marked edema. The resulting pressure may cause pressure on critical structures. . . .
>
> When acute absorbed skin doses in the range of 7 to 50 GY (700 to 5000 rad) are received, the gastrointestinal syndrome (group IV) may occur. In most circumstances, after the prodromal period, a latent period of approximately 1 to 4 days during which the patient is asymptomatic occurs. The clinical progress of the syndrome is a manifestation of the radiosensitivity and failure of both the gastrointestinal syndrome and the bone marrow. The symptoms include lethargy, diarrhea, dehydration, and sepsis. The earliest pathologic changes can be identified as degenerative abnormalities in the small bowel epithelium. . . .

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is modified rather than killed. Chernobyl Report at 39-40. The modified cell replicates itself, and over time, may develop into cancer. The risk of contracting cancer as a result of radiation exposure increases in relation to the dose of radiation to which a person is exposed. See generally, Chernobyl Report at 40-41 ("[F]atal cancer risk factor following exposure to relatively low doses delivered at low dose rates is smaller than the values assessed for high doses at high dose rates."); BEIR V at 20-24 (discussing radiobiological concepts impacting on biological consequences of a given dose of radiation). Accordingly, to determine the effect that radiation exposure will have on a person, it is necessary to quantify the dose of the exposure.

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> In the absorbed skin dose range of 2 to 7 GY (200 to 700 rad), the hematopoietic syndrome (groups II and III) may be encountered. After the prodromal period, the duration of the asymptomatic latent period is 1 to 3 wks. The signs and symptoms result from radiation damage to the bone marrow, lymphatic organs, and immune response. In this syndrome, rapid reduction in the lymphocytes and a somewhat more delayed reduction of leukocytes, platelets, and red cells occur. The granulocytopenia leads to infection, and the thrombocytopenia leads to hemorrhage. Mean survival is usually 2 to 6 wks, with the nadir of the various blood elements occurring approximately 30 days after exposure. Death usually results from hemorrhage and infection.

Fred A. Mettler, Jr., M.D. and Arthur C. Upton, M.D., Medical Effects of Ionizing Radiation 279-80 (W.B. Saunders Co. 1995) (D-X-155) (hereinafter "Medical Effects").

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The following dosimetric quantities are used within the field of health physics to express exposure:

> Absorbed dose: The amount of radiation energy that is absorbed per kilogram of tissue. It is expressed in grays (Gy).
>
> Equivalent dose: The absorbed dose weighted for the harmfulness of different radiations (by radiation weighting factors) to take into account the different types of radiation and their energies. It is expressed in sieverts (Sv), with submultiples of millisieverts (mSv). . . . For most practical applications, the radiation weighting factor is unity; that is, the numerical values for absorbed dose and equivalent dose will be equal.
>
> Effective dose: The equivalent dose weighted for the susceptibility of harm of different human tissues. It is a (modified) equivalent dose and is also expressed in sieverts.

Chernobyl Report at 21.

Although uncertainties remain, the last decade has seen tremendous advances in what is known about radiation induced cancers. See BEIR V at 1 ("Since the completion of the 1980 BEIR III report, there have been significant developments in our knowledge of the extent of radiation exposures from natural sources and medical uses as well as new data on the late health effects of radiation in humans. . . . Furthermore, advanced computational techniques and models

for analysis have become available for radiation risk assessment."). Long term studies on the survivors of Hiroshima and Nagasaki, British akylosing spondylitis patients treated with radiation therapy, and other persons exposed to radiation via nuclear weapons testing or occupational exposures, have increased the body of knowledge regarding the health effects of radiation exposure. See United Nations Committee on the Effects of Atomic Radiation ("UNSCEAR"), "Sources and Effects of Ionizing Radiation" at Appendix F, p. 620 (1993) (hereinafter "UNSCEAR 1993").[14] Based upon these advances, and relying upon the findings of these authoritative compilations, the National Research Council in 1995 published a comprehensive handbook on the mechanics of dose reconstruction. Radiation Dose Reconstruction for Epidemiologic Uses (1995) (hereinafter "Radiation Dose Reconstruction").[15]

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14. The O'Conner court provided the following statement about UNSCEAR:

> The United Nations Committee on the Effects of Atomic Radiation (UNSCEAR) was established by the United Nations General Assembly in 1955. The committee is made of eminent experts in the field of radiation from the international scientific community. It periodically issues Reports (sic) that summarize the main conclusion of all of the world's published scientific literature in the field. These reports of consensus science can be used to measure the validity of the claims of litigants.

Id. at 1382 n. 3 (citation omitted).

15. The preface describes the goals of the publication as follows:

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Radiation Dose Reconstruction focuses on the process of reconstructing a dose from a past exposure to radiation to provide a basis for estimating health risks arising from the exposure. Id at 7. As such, it is well suited to serve as a framework for evaluating the evidence in the captioned matter. The following "steps" are identified in Radiation Dose Reconstruction as integral to any dose reconstruction analysis:

> *Source term[16] analysis consists of estimating the magnitude of releases to the environment of

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> As public concern mounts over past and current exposure to ionizing radiation stemming from environmental releases of radioactive materials, there is a growing need to define the criteria to be met by studies that reconstruct exposures and doses and to provide guidance in the studies' epidemiologic use. Absent this, dose reconstruction studies are not likely to stand serious scientific scrutiny or to meet public concerns . . . . This report should set the objectives to be attained by such studies and provide guidelines for their conduct. It is aimed at providing generic information to scientists entering the field and to interested members of the public.

Radiation Dose Reconstruction at vii (emphasis added).

16. "The source term is the amount of radionuclides released from a site to the environment over a specific period. The rate of release as a function of time should also be determined. Releases can be to the atmosphere, to surface waters, to groundwater, or to soil." Radiation Dose Reconstruction at 16.

radionuclides and the periods over which they were released, including episodic releases from nonroutine events.

*Pathway analysis examines the transport of released radionuclides through environmental pathways to determine their concentrations in environmental media to which people were exposed. These media include air, surface and groundwater, and soil, among others.

*Assessment of radiation doses and risks brings together all of the data on releases, transport, lifestyle and dietary habits, analysis of agricultural and food-distribution practices, and biologic factors, including the use of biologic dosimetry, to determine doses or to corroborate evidence of doses and to estimate the likelihood of disease in the exposed persons.

*Examination of epidemiologic considerations takes into account the size and demographic structure of the potentially affected population, the availability and quality of information needed to estimate the dose, the medical information needed, and the feasibility of conducting an investigation that is sufficiently informative and free of bias.

*Uncertainty and sensitivity analysis identifies the importance of changes in the parameters and

values used to estimate confidence intervals[17] in the overall analysis of the dose reconstruction. . . .

Radiation Dose Reconstruction at 9 (footnote added; emphasis in original). It is also noted that "[h]istoric records are commonly the foundation of a dose reconstruction project, and [that] it is always preferable to use measured data (historic data) rather than models in reconstruction of doses." Id. at 10. Finally, the report stresses that "[d]ose reconstruction studies must rely on solid science, state-of-the-art methods, and careful peer review if they are to be viewed as credible. Ultimately, a dose reconstruction study will be judged by the scientific community primarily on the basis of the technical quality of the study and its contribution to science." Id. at 14.

c. Risk Assessment

Once a dose reconstruction analysis is performed, it is possible to make a risk assessment based upon the calculated exposure level. Risk assessments of this nature are made by reference to, among other things, "dose-response curves" which delineate the connection between radiation exposure at various doses and cancer induction. Stated in the most general terms, UNSCEAR and the ICRP recognize the

17. A "confidence interval" is "[a]n estimate, expressed as a range, for a quantity in a population. If an estimate from a large sample is unbiased, a 95% confidence interval is the range from two standard errors below to two standard errors above the estimate. Intervals obtained this way cover the true value about 95% of the time. . . ." Reference Manual on Scientific Evidence at 396 (Fed.Judicial Ctr. 1994) (hereinafter "Reference Manual").

"curve" for solid cancers to be linear[18], while the "curve" for leukemias is recognized to be linear-quadratic.[19] See

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18. "The linear model suggests that each time energy is deposited in the susceptible target there is a probability of [tumor] initiation." Medical Effects at 81. The Johnston court explained the linear curve as follows:

> If one assumes that the risk per rem is the same at low doses as it is at high doses, one is assuming that if a million people exposed to 100 rem will have 10 excess cancers, then a million people exposed to 10 rem will have one excess cancer. When such an assumption is drawn on a standard dose response graph, the result is a straight line. This assumption is known as the linear hypothesis.

Johnston v. United States, 597 F.Supp. 374, 393 (D.Kan.1984) (citing BEIR III at 520).

19. The linear quadratic curve presumes that all reactions are dose-dependent. See Medical Effects at 81 ("Because each of these factors may change differently with dose, the risk and shape of the curve in a certain dose region cannot be extrapolated with certainty either up or down. . . ."). In Johnston, the court provided the following explanation of both quadratic and linear quadratic curves:

> In the field of radiation science, the linear hypothesis and the threshold hypothesis are not the only theories used by respected scientists to predict the carcinogenic effect of radiation. There is also the quadratic hypothesis which suggests that a low dose of radiation is less carcinogenic per rad than a high dose of radiation. When the quadratic hypothesis is drawn on a standard dose response graph, the result is a downward dipping curve.

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BEIR V at 140-44 ("The dose-response relationship for the induction of radiogenic transformation reflects a balance between an increase with dose in the proportion of cells that are transformed and a decrease in cell survival."); Medical Effects at 82 (explaining linear, quadratic and linear-quadratic dose-response curves). The scientific literature is in agreement that no study has shown a dose-response relationship at doses under 10 rems. See BEIR V at 4-5; Medical Effects at 86 ("there is, in fact, no proven body of data that established an increase in human cancer levels below about 0.1 Gy (10 rad)); see also UNSCEAR 1994 at 50-60 (Annex A) (summarizing the findings of epidemiological studies attempting to establish a dose-response relationship following exposure to low-LET radiation); UNSCEAR 1993 at 676, 679-80 (Annex F); Chernobyl Report at 41 ("statistically significant direct observations in man in homogenous populations . . . are available for doses down to about 200 mSv."). Moreover, at doses below 10 rads, biological markers of dose[20] and

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> Another theory is the linear-quadratic hypothesis. This one blends aspects of the linear hypothesis with aspects of the quadratic hypothesis. It yields a curved line on a standard dose response graph which falls between the linear line and the quadratic curve.

Johnston, 597 F.Supp. at 393 (citing BIER III at iii).

20. "[E]xposure can be estimated from dose, which in turn can be reconstructed through internal indicators (biomarkers . . .) after the exposure has taken place." Environmental Protection Agency Guidelines on Exposure Assessment, 57 Fed.Reg. 22,888, 22,898 (Cont'd)

exposure become less helpful as indicators. Radiation Dose Reconstruction at 58 ("For retrospective dose reconstruction, it is generally agreed that markers of exposure are not useful below an acute dose of 0.1 Gy (10 rad)."); see generally id. at 51-59. Accordingly, the most that scientists can do is extrapolate and speculate regarding the dose-response relationship at such low levels of exposure. In addition to the dose-response curves, risk assessments must consider a number of factors that could increase or decrease a person's propensity to develop cancer following radiation exposure. These factors include, but are not limited to: age at the time of exposure, sex, genetic predisposition, whether the individual smokes, and the possibility of exposure to other toxic agents. See Radiation Dose Reconstruction at 48; ICRP 60 at 120-22; EPA Guidelines at 22,900. Finally, a

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(May 29, 1992) (hereinafter "EPA Guidelines"). These markers include chromosome "aberrations, micronuclei, DNA adducts, or mutations." Radiation Dose Reconstruction at 51. It is further noted that:

> There are three kinds of biologic markers: markers of exposure or dose, markers of effect, and markers of susceptibility. Biologic markers of effect record biologic responses in individuals who have been exposed to a genotoxic agent, but markers of exposure (or dose) do not necessarily indicate effects. Superimposed on this are markers of susceptibility; those that could be used to identify persons who are at increased risk of developing a disease that could be triggered by a given exposure.

Id. at 51-52.

comprehensive dose assessment depends upon the calculation of an organ dose. Id. at 47 ("The organ dose is especially important when developing doses to compare to site-specific health effects.") Knowledge of the type of radionuclide to which an individual was exposed is relevant when calculating organ dose. See Allen, 588 F.Supp. at 308 ("Once ingested or inhaled, the degree of exposure actually experienced depends upon the highly variable physical and chemical qualities of each individual radionuclide.").

3. Principles Relevant to a Nuclear Reactor Accident

a. Pressurized Water Reactors

The basic principles associated with the operation of pressurized water reactors ("PWR") are not at issue in this case (although the specific operation of the TMI-2 PWR during the accident is). An understanding of these basic principles is necessary to understand the release and source term evidence in this case. Plaintiffs, however, have not introduced evidence providing a description of these basic principles. The court's searching review of the record has revealed one governmental report and one affidavit that explain these principles in layperson's terms. Since the basic operation of a pressurized water reactor is not at issue in the litigation, the court finds it proper to rely on the following excerpt from the Daniel affidavit for its educational value:

> A nuclear power plant produces heat energy that is converted to steam in a boiler. The steam is used to turn a turbine, which is connected to an

electrical generator. The heat is produced in a steel vessel called a reactor, since nuclear reactions are contained within the vessel. In a reactor design such as TMI-2, uranium fuel is used to provide the heat energy. The fuel is formed into a ceramic pellet approximately 1/2 inch in diameter, and about a half-inch long. These pellets are stacked into metal rods called fuel pins, and the fuel pins are arranged into square arrays called fuel assemblies. The fuel assemblies are approximately 12 feet in height, and are collectively referred to as the reactor core contained in the reactor vessel. Within the fuel assemblies are several tubes which have instruments to monitor the reactor and other tubes that contain control rods which "speed up" or "slow down" the reaction. The fuel pellets are protected from direct contact with water in the core by the rods made of zirconium, which is sometimes called the fuel cladding. . . .

In a pressurized water reactor, such as TMI-2, there are three cooling circuits. The primary circuit is a closed loop circuit and circulates water through the reactor core. This circuit is called the primary coolant or reactor coolant. The reactor coolant is maintained at a pressure that is high enough to prevent it from boiling. The reactor coolant picks up the heat from the fission reaction and carries it out of the core to two steam generators (or boilers). These are tanks approximately 35 feet tall in which the primary

water passes through a large number of small diameter tubes, transferring heat to water flowing in the secondary circuit, which is outside these tubes. Water in the secondary circuit is maintained at a lower pressure and boils to make steam which occupies much more volume than water. That steam therefore "pushes" itself out at high velocity to the turbine-generator unit. The steam in the secondary circuit is called the main steam system. The steam passes from the turbine to a condenser which is cooled in turn by the third circuit, water from the cooling towers. Water collected in the condenser is pumped back to the steam generators. The water in this portion of the secondary circuit is called feedwater.

The water in the primary loop is kept from boiling by keeping it under high pressure — normally about 2200 pounds per square inch. A large vessel connected to the primary loop called the pressurizer is used to maintain this pressure. The pressurizer is normally about half full of water, with a steam cushion in the top half. As the water in the primary loop heats up or cools down, it expands or contracts by many hundreds of cubic feet. The steam cushion in the pressurizer takes up the slack, while maintaining pressure on the reactor coolant water.

The control system adjusts the pressure exerted by the pressurizer by controlling the temperature of the water in the pressurizer with electric

heaters, and with a cooling water spray. A relief valve is provided on the pressurizer to prevent overpressurizing the system. This valve is a power-operated relief valve, or PORV. If this valve is opened to relieve the excess pressure, the steam or water flows to a drain tank. If the drain tank becomes over filled, a rupture disk is provided on the tank to relieve pressure. The relief valve has a backup, which is called a block valve. Additionally, two large safety valves provide protection against larger transients.

The reactor coolant may have chemicals added to it for fine adjustment of the nuclear reaction taking place in the reactor core, and to remove any impurities that may have collected in the coolant. During power operation, a small flow of reactor coolant is bled off from the reactor coolant system and passed through a series of filters and demineralizers. If any additional water is needed in the reactor coolant system, it is added from water stored in tanks located in the auxiliary building. The system that collects water from the reactor coolant system and adds water to the reactor coolant system is called the makeup purification system. Gases collected from the reactor coolant system are collected in tanks called waste gas decay tanks. . . .

The reactor vessel, pressurizer, associated piping, reactor coolant pumps, and steam generators are called the reactor coolant system. The reactor

> vessel is a steel pressure vessel with walls that are 8 1/2 inches thick, surrounded by a concrete and steel shield over 8 feet thick. The reactor coolant system is housed in a cylindrical building, which is actually a large pressure vessel called the reactor building. The turbine, condenser, and electrical generator are housed in a concrete and steel building called the turbine building. Auxiliary systems used to process and maintain the chemical and radiological purity of the reactor coolant are housed in what is called the auxiliary building. The fuel handling building, as its name implies, contains storage facilities for new and used fuel. The used fuel, after removal from the reactor core, is stored underwater in the spent fuel pool. The plant operators monitor and maintain control of the various plant systems from a central control room located in the control service building.

4/28/93 Aff. of John Daniel at ¶ 17, ¶¶ 19-25 (emphasis in original); see also Mitchell Rogovin, Nuclear Reg. Comm'n Inquiry Group, NUREG/CR-1250, TMI Report to the Commissioners and to the Public 10-13 (1980) (section titled "Primer on the Pressurized Water Reactor: From A-Loop to Zircaloy") (hereinafter "Rogovin Report").

b. Plume Dispersion

Once fission product noble gases are released into the atmosphere, the path that they travel and the degree of concentration that they maintain over a given distance can

be determined through the use of dispersion modeling and the science of meteorology. "Atmospheric dispersion modeling is really the development of mathematical relationships that describe how something that's from material that's released into the atmosphere is dispersed as it travels downwind." (11/13/95 Tr. at 149 (testimony of Keith Woodard).) The following explanation of basic dispersion modeling (with specific attention paid to a model used in evaluating the TMI plume) is illustrative:

> The basic function of the model is to calculate dispersion (dilution) of the released material as it travels downwind and to estimate the resulting concentrations of this material at ground level. The material is considered to form a "plume" as it is transported downwind. This plume trajectory (or travel direction) changes, depending on meteorological measurements of wind speed and direction updated every 15 minutes. The plume size depends on turbulence. As turbulence increases, the plume becomes larger and more dilute. Turbulence is based on vertical temperature difference measurements from the meteorological tower. Generally, turbulence increases in the daytime and decreases at night.
>
> The model assumes an initial elevation and plume spread depending on the effects nearby buildings have on the wind streamlines in relation to the release location (the plant vent in this case). Depending on the flow rate from the plant vent and the wind speed, the plume is divided into

small segments called spatial intervals according to the travel distance for the 15-minute period. Plume dispersion is estimated at the center of each segment based on the weather measurements. The time it takes for the cloud to arrive at, and to traverse, each spatial interval is calculated using the average wind speed for that interval. Whenever there is a change in stability, the new spatial interval rate of growth is based on the new stability.

(1/15/93 Aff. of Keith Woodard at ¶¶ 14-15)

C. Factual Background

The accident at TMI-2 began . . . at 4 a.m. on March 28[, 1979]. A minor malfunction, or transient, in the nonnuclear part of the system would evolve a series of automated responses in the reactor's coolant system, and during all of this, the relief valve on top of a piece of equipment called "the pressurizer" would become stuck open. Owing to continued misreading of the symptoms by the operators over a 2 1/4-hour period before the relief valve was closed and the turning off of an automatic emergency cooling system, the reactor core would become partially uncovered and severely damaged. It would be another 12 hours before the plant crew and the engineers from GPU Service Company would concur in effective corrective action.

Rogovin Report at 3-4. During the incident, radiation was emitted from the Unit-2 reactor. The actual amount emitted, and whether Plaintiffs were exposed to the emissions, are central issues in this case. According to the Rogovin Report, "approximately 2.5 million curies of radioactive noble gases and 15 curies of radioiodines were released. . . . These releases resulted in an average dose of 1.4 mrem to the approximately two million people in the site area." Rogovin Report at 153.[21] Plaintiffs, to the contrary, contend that area residents were exposed to in excess of 100 rems of radiation. Defendants have conceded that releases at the plant boundaries exceeded normal levels of background radiation, In re TMI Cases Consolidated II, 67 F.3d 1103, 1118 (3d Cir.1995). However, Defendants deny that appreciable or dangerous levels of radiation reached populated areas.

Plaintiffs' theory of the case is that a narrow yet highly concentrated plume of radioactive noble gases (primarily iodine and xenon-133) was carried away from the TMI plant during one or all of three hypothesized "blowout" periods.[22] Plaintiffs' argue that prevailing weather conditions permitted the plume to drift through the atmosphere, moving between the thermoluminescent dosimeters ("TLDs")[23] which

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21. Other state and federal government reports, discussed infra, corroborate the findings of the Rogovin Report.

22. Plaintiffs' expert David Lochbaum has indicated three potential "blowout" periods, but is unable to say with certainty that any blowout did in fact occur. (Compare 1/22/96 Lochbaum Report at 14 with 3/5/96 Tr. at 1455-56 (testimony of David Lochbaum).)

23. TLDs are instruments used to measure airborne radiation. The Ad Hoc Group Report gave the following technical description

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composed the TMI Radiation Environmental Monitoring Program ("REMP"), and caused the plume to remain highly concentrated for a significant distance. Plaintiffs contend that the plume made contact with higher land elevations within the TMI area, and that persons residing in areas of plume

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(Cont'd)
of the TLDs that comprise the TMI Radiation Environmental Monitoring Program:

> All 20 of the Metropolitan Edison locations had environmental TLD's manufactured and read by Teledyne Isotopes. These Teledyne Isotopes environmental dosimeters are rectangular Teflon wafers impregnated with 25% CaSO4:Dy phosphor contained in black polyethylene pouches in rectangular holders with copper filters to make the energy response more uniform ("flatten" the energy response). After exposure in the environment, measurements of the exposure are made on each of four separate areas of the dosimeter. The average of these four readings is used in the calculations. In the product bulletins, these dosimeters are said to have a "minimum sensitivity" of 0.5 mR and to have a "maximum error (1 standard deviation)" of "[plus or minus] .2 mR or [plus or minus] 3%, whichever is greater" for measurement of exposure from cobalt-60 gamma radiation.

Ad Hoc Population Dose Assessment Group, Population Dose and Health Impact of the Accident at the Three Mile Island Nuclear Station 13 (1979). The Rogovin Report indicates that the "TLDs provide the best estimate of the integrated radiation dose at a specific location, and can yield a source term when an isotopic spectrum and meteorological conditions are considered." Rogovin Report at 358.

touchdown were exposed to harmful levels of ionizing radiation.[24]

Plaintiffs claim that they have developed radiation induced neoplasms[25] as a result of their exposure to ionizing radiation during the TMI incident. The parties agree that the following test Plaintiffs have been diagnosed with the illnesses listed:

Paula Obercash:	acute lymphocytic leukemia
Gary Villella:	chronic myelogenous leukemia
Leo Beam:	chronic myelogenous leukemia
Joseph Gaughan:	thyroid cancer
Lori Dolan:	Hurthle cell carcinoma
Jolene Peterson:	thyroid adenoma

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24. A typographical error in the court's January 5, 1996 Daubert ruling characterizes Plaintiffs' theory as stating that a majority of releases traveled in a northeasterly, rather than in a north-northwesterly direction. In re TMI, 911 F.Supp. at 786.

25. A "neoplasm" is defined as:

> an abnormal tissue that grows by cellular proliferation more rapidly than normal and continues to grow after the stimuli that initiated the new growth cease. N[eoplasm]s show partial or complete lack of structural organization and functional coordination with the normal tissue, and usually form a distinct mass of tissue which may be either benign (benign tumor) or malignant (carcinoma).

Stedman's Medical Dictionary 931 (5th unabridged lawyer's ed. 1982).

Appendix D

Ronald Ward:	osteogenic sarcoma (right leg)
Pearl Hickernell:	breast cancer
Ethelda Hilt:	adenocarcinoma of the ovaries
Kenneth Putt:	bladder cancer, acoustic neuroma.

Defendants contend that Plaintiffs have failed to establish that any of the test Plaintiffs' neoplasms are causally related to radiation exposure during the TMI incident.

II. Legal Standards

The instant motion for summary judgment will be considered pursuant to Rule 56 of the Federal Rules of Civil Procedure. Summary judgment is appropriate where there are no remaining issues of material fact to be decided, and one party is entitled to judgment as a matter of law. Hankins v. Temple University, 829 F.2d 437, 440 (3d Cir.1987). In examining Rule 56 motions, the court must consider "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 251-52, 106 S.Ct. 2505, 2512, 91 L.Ed.2d 202 (1986).

The parties' burdens at summary judgment may be described in the following manner; once the moving party has shown an absence of evidence to support the claims of the nonmoving party, the nonmoving party must do more than simply sit back and rest on the allegations of her complaint. She must "go beyond the pleadings and by her own affidavits, or by the 'depositions, answers to interrogatories, and admissions on the file,' designate

'specific facts showing that there is a genuine issue for trial' " Celotex Corp. v. Catrett, 477 U.S. 317, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). If the nonmovant bears the burden of persuasion at trial, the moving party may meet its burden by showing that the evidentiary materials of record, if reduced to admissible form, would be insufficient to carry the non-movant's burden at trial. Chipollini v. Spencer Gifts, Inc., 814 F.2d 893, 896 (3d Cir.), cert. dismissed, 483 U.S. 1052, 108 S.Ct. 26, 97 L.Ed.2d 815 (1987). "The mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient; there must be evidence on which the jury could reasonably find for the plaintiff." Anderson, 477 U.S. at 252, 106 S.Ct. at 2512.

In a case dependent upon expert scientific testimony, the court must determine whether the admissible scientific testimony is sufficient to carry the nonmovant's burden at trial. The Supreme Court, in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 595, 113 S.Ct. 2786, 2798, 125 L.Ed.2d 469 (1993), noted as follows:

> in the event the trial court concludes that the scintilla of evidence presented supporting a position is insufficient to allow a reasonable jury to conclude that the position more likely than not is true, the court remains free to direct a judgment . . . , and likewise to grant summary judgment. . . . These conventional devices, rather than wholesale exclusion under an uncompromising "general acceptance" test, are the appropriate safeguards where the basis of scientific testimony meets the standards of Rule 702.

Id.; see also DeLuca v. Merrell Dow Pharmaceuticals, Inc., 911 F.2d 941, 958 (3d Cir.1990) ("[the] court . . . must ultimately determine whether the admissible evidence tendered by the party having the burden of proof on an issue is sufficient to permit a rational factfinder to find for that party on that issue under the appropriate burden of proof"); Wade-Greaux v. Whitehall Laboratories, 874 F.Supp. 1441, 1485 (D.V.I.) ("Even when a court determines that expert opinion evidence is admissible, it must still determine whether it would be sufficient to sustain a jury verdict in plaintiff's favor."), aff'd, 46 F.3d 1120 (3d Cir.1994); cf. Ambrosini v. Upjohn Co., 1995 WL 637650 at *1 n. 1 (D.D.C. October 18, 1995) ("The [District of Columbia] Court of Appeals has stressed that the admissibility of an expert's opinion is 'separate and distinct from the issue whether the testimony is sufficient to withstand a motion for summary judgment.' " (citation omitted)).

III. Discussion

In this section, the court will first discuss its examination of the record evidence supporting both Defendants' and Plaintiffs' cases. Next, the court will explain the elements of Plaintiffs' prima facie case, and discuss the degree to which Plaintiffs have presented evidence in support of that case. Finally, the court will discuss its finding that Plaintiffs have failed to present evidence sufficient to create a material factual dispute on the issue of dose. At the outset, it is important to note that the scientific evidence must be viewed through the framework set forth by the court in the scientific background section of this memorandum of law. Thus, the court must first examine whether source term evidence has

been presented to support the theory that there was a release from the plant during the accident. Next, the court must determine whether there is evidence demonstrating whether Plaintiffs were exposed to the release, and if so, whether there is evidence illustrating the pathways through which Plaintiffs were exposed. Finally, the court will evaluate whether the record evidence is sufficient to support the inference that radiation exposure induced the test Plaintiffs' subsequent health effects (neoplasms).

A. The Defendants' Case

Defendants attack Plaintiffs' evidence of exposure and dose arguing that, reduced to admissible form, the evidence is insufficient for Plaintiffs to meet their burden of proof on the issue of causation at trial. (Defs.' Mem. in Supp. of Motn. for Summ.J. at 126-32 (hereinafter "Defs.' Mem. in Supp.").)

1. Exposure/Dose Evidence

Defendants have offered John Daniel, a nuclear engineer, as their source term expert. Daniel "was engaged by counsel for defendants to study the sequence of events, possible pathways of releases, and magnitude of releases during the TMI accident." (Defs.' Mem. in Supp. at 42 (footnote omitted).) Daniel will testify regarding the in-depth analysis he performed on all relevant plant data and the "time line" of key events that he derived from that analysis. According to Defendants, the time line will chronicle the "events that occasioned the transport of radioactivity to the Aux[iliary] Building and the release of that radioactivity into the

Aux[iliary] Building atmosphere." (Defs.' Mem. in Supp. at 48.)[26] According to Daniel's calculations:

> approximately 17 million curies[27] of noble gas were transported to the auxiliary building by all pathways during the accident, of which

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26. At the outset of his report, Daniel states the following purposes of the report:

> It is our purpose to identify how radioactive gases were transported and were eventually released from the plant. In short, this report is intended to reconstruct what happened inside the plant during the accident, and to determine, from that information base, the maximum credible source term for release to the environment as it occurred. This report describes the events and releases that occurred from initiation of the accident at 4:00 a.m. on March 28th, 1979 until 6:00 a.m. on April 7th, 1979, and accounts for more than 99% of the releases from the plant.

(4/28/93 Aff. of John Daniel at Ex. A, p. 1 (filed on 5/4/93 as "Revised Exhibit B" to Defendants' motion for summary judgment as to all Plaintiffs based on compliance with federal safety regulations and the supporting memorandum of law) (hereinafter 4/28/93 Daniel Report").)

27. "The curie is a special unit of activity. One curie (abbreviated Ci) is equal to 37 billion disintegrations per second." (7/12/95 Aff. of John Fraizer at ¶ 37.) The total quantity of radioactive material released into the environment in the operation of a nuclear power plant is measured in curies. Akins v. Sacramento Municipal Utility District, 8 Cal.Rptr.2d 785, 785-90 (Cal.Ct.App. 1992), rev. dismissed, 28 Cal.Rptr.2d 150, 868 P.2d 905 (1994).

> approximately 14 million curies were transported during the first 48 hours. Of the 17 million curies transported to the auxiliary building, 8.6 million curies were released to the environment by all pathways during the period 4:00 A.M. on March 28th, 1979 to 6:00 A.M. April 7th, 1979. This quantity represents more than 99% of the total activity released from TMI-2 as a result of the accident. The predominant radionuclide release to the environment was Xe-133. The remaining 8.4 million curies of noble gas were either transferred back into the reactor building by the plant operators, or were contained in tanks in the auxiliary building.

(4/28/93 Aff. of John Daniel at ¶ 35 (footnote added).) After examining all potential pathways for release, Daniel reached the conclusion that the pathway for fission products from the coolant to the reactor building was through the power-operated relief valve ("PORV").[28] (4/28/93 Daniel Report at 99.) "[T]he major pathway for fission product transport [from the reactor building] to the auxiliary building was through the letdown piping of the makeup and purification system." (4/28/93 Daniel Report at 33.) It is through this pathway that approximately 17 million curies were transferred to the auxiliary building; and, of that 17 million, approximately 8.6 million were released to the

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28. The PORV "is provided on the pressurizer to prevent overpressurizing the system. If this valve is opened to release the excess pressure, then steam or water flows to a drain tank [in the reactor building]." (4/28/93 Daniel Report at 99.)

environment.[29] (Id. at 34.) Daniel concludes that the primary release pathway from the auxiliary building to the environment was through plant ventilation systems. (Id. at 60.)

In addition to determining how radioactive noble gases were released into the atmosphere, Daniel computed the core inventory of fission products to determine the quantities of specific radionuclides that were released into the environment. Daniel utilized the LOR2 computer code to calculate the core inventory. (Id. at 81.) According to his report, Daniel found this code to be the most accurate because it accounted for the concentration of boron[30] in the reactor coolant during periods of irradiation, "factored in the actual operating history of the TMI-2 core, [and] accounted for the different power levels that the actual core experienced." (Id.) Table 3.2 of the 4/28/93 Daniel report provides a breakdown of the core inventory of selected fission products at the time

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29. Daniel also notes that approximately 150,000 curies of fission product noble gases were transported to the auxiliary building through the action of venting the reactor coolant drain tank to the reactor building vent header. Because the reactor building vent header is connected to the auxiliary building waste gas vent header through isolation valves, venting into the auxiliary building can occur through the isolation valves when certain conditions are met. According to Daniel, the isolation valves connecting the auxiliary building were open between 7:14 a.m. and 7:18 a.m., and between 7:44 a.m. and 7:56 a.m., on March 28, 1979. (4/28/93 Daniel Report at 31-32.)

30. "The concentration of boron is directly related to the neutron population in the core, and is therefore an important factor in determining fission product inventory." (4/28/93 Daniel Report at 81.)

of reactor shutdown. (Id. at 83.) By calculating the core inventory, Daniel was able to determine which noble gases were transported into the auxiliary building and then to the environment.

Defendants rely upon the proffered testimony of Keith Woodard to explain how the approximately 9 million curies of radioactive noble gases released from the plant were dispersed into the environment. In addition, based upon his dispersion analysis, Woodard has made individual whole body dose calculations for each of the ten test Plaintiffs. Woodard is the vice president of Pickard, Lowe & Garrick, Inc. ("PLG"), a consulting/engineering firm specializing in the field of meteorological dispersion studies. (1/15/93 Aff. of Keith Woodard at ¶ 1.)[31] During the TMI accident, Woodard worked with emergency response teams to perform dose assessments to support the on-site response organization. (Id. at ¶ 4.) Additionally, following the accident, Woodard studied offsite exposures and reported his findings in a document titled, "Assessment of Offsite Radiation Doses from the Three Mile Island Unit 2 Accident," TDR-TMI-116, Revision O (July 31, 1979) (hereinafter "TDR-TMI-116"). (Id. at ¶ 5.)

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31. Woodard has bachelors and masters degrees in Nuclear Engineering. (1/15/93 Aff. of Keith Woodard at ¶ 2.) Prior to his present employment, Woodard was employed as a project leader in the Atomic Energy Commission's Division of Reactor Licensing. In that capacity he was responsible for safety analysis and evaluation of nuclear power and research reactors. (Id.) Since 1967 he has been employed by PLG working on conducting safety evaluations related to the environmental impact of radiation releases. (Id.) Woodard has extensive experience with the use and development of computerized atmospheric dispersion models.

Appendix D

At the request of counsel for Defendants, Woodard performed two separate studies. The first study utilizes the Daniel source term and the Meteorological Information and Dose Assessment System dispersion model ("MIDAS")[32] to calculate the percentage of the NRC's Maximum Permissible Concentration ("MPC")[33] in the TMI area. Woodard also calculates whole body dose levels using the Daniel source term. The second study also uses MIDAS, but uses the source term methodology employed in TDR-TMI-116 rather than the Daniel source term. (Id. at ¶ 8.) Woodard's studies both indicate that dangerous levels of radiation (e.g. greater than the NRC MPC's for one year) did not reach populated areas beyond the plant boundaries. Rather, Woodard contends, the highest concentrations of radiation were found on the Island itself, in a portion of the Susquehanna River, and on uninhabited islands in the river. (Id. at ¶¶ 22-23.) Woodard

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32. According to Woodard, MIDAS is PLG's most advanced computer dispersion model. (1/15/93 Affidavit of Keith Woodard at ¶ 6.)

33. Woodard describes MPC as follows:

> Title 10 of the Code of Federal Regulations, part 20.106 (10 CFR 20) provides permissible concentrations of radionuclides in areas normally occupied by the general public. These concentrations are based on calculations of radiation exposure (dose) that a person would receive if immersed in air containing the permissible concentration averaged over a period of 1 year. These regulations were established to limit the annual dose to the public to acceptable levels.

(Id. at ¶ 9.)

states that the outcomes of his studies are confirmed by comparing them with offsite TLD[34] measurements and with the inventory of noble gases found in the containment and fuel following the accident. (Id. at ¶¶ 30-31.)

Finally, based upon his dispersion calculations, Woodard calculated whole body doses for each of the test Plaintiffs. Viewing the facts in a light most favorable to Plaintiffs, the court will presume Woodard's "high" dose estimates to be true. According to those estimates, only one of the ten test Plaintiffs was exposed to a dose greater than 25 mrem. That Plaintiff, Jolene Peterson, was exposed to an estimated maximum dose of 75 mrem. Four of the test Plaintiffs, Pearl Hickernell, Ethelda Hilt, Leo Beam and Ronald Ward, were exposed to estimated maximum doses under 10 mrem. The remaining test Plaintiffs, Gary Villella, Lori Dolan, Joseph Gaughan and Paula Obercash, were exposed to estimated maximum doses of between 15 and 25 mrem. These dose calculations are based upon the Daniel source term, do not make any attempt to adjust for possible shielding,[35] and account for changes in each Plaintiff's physical location over time. (7/12/95 Woodard Report at 39.)

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34. A "TLD," or thermoluminescent dosimeter, is used to measure airborne radiation. For a more detailed description of the TLDs used in the TMI REMP, see supra note 23.

35. Shielding occurs, for example, when one is inside a building when a radioactive cloud passes overhead. The person inside of the building would be shielded, thus receiving a lower dose of radiation than someone standing outdoors at the same location during the same time period.

Appendix D

Defendants also rely on a number of governmental reports in support of their position on the issue of dose. The first of these is the report of the Ad Hoc Population Dose Assessment Group.[36] This report "is an assessment of the health impact on the approximately 2 million offsite residents within 50 miles of the Three Mile Island Nuclear Station from the dose received by the entire population (collective dose)." Ad Hoc Population Dose Assessment Group, "Population Dose and Health Impact of the Accident at the Three Mile Island Nuclear Station" at preface (May 10, 1979) (D-X-33) (hereinafter "Ad Hoc Group Report"). The Ad Hoc Group relied upon TLD data and onsite meteorological data to compile conservative dose estimates. Id. at 1-2. Noting that "any approach to assessing the collective dose depends strongly on a relatively small number of measurements," id. at 41, the Ad Hoc Group nevertheless found that "the data do allow reasonable estimates of the collective dose[37] to be

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36. The group was comprised of representatives from the Environmental Protection Agency ("EPA"), the Department of Health Education and Welfare ("HEW") (now the Department of Health and Human Services), and the NRC. (Defs.' Mem. in Supp. at 53-4.)

37. According to the Ad Hoc Group Report,

> The Collective dose is a measure of the total radiation dose which was received by the entire population within a 50-mile radius of the Three Mile Island site. It is obtained by multiplying the number of people in a given area by the dose estimated for that area and adding all these contributions.

Id. at 5.

made." Id. (footnote added). It is presumed that the greatest degree of exposure came from xenon. Id. at 11 ("The principal radioactive materials released to the environment appear to be xenon-133 (half-life 5.3 days) and xenon-135 (half-life 9.2 hours) and traces of radioactive iodine, primarily iodine-131 (half-life 8.0 days)"). Milk and food samples taken during the period of March 31, 1979 through April 4, 1979, one week after the accident, confirm this hypothesis:

> The maximum concentration [of iodine] measured in milk (41pCi/liter in goat's milk, 36 pCi/liter in cow's milk) was 300 times lower than the level at which the Food and Drug Administration (FDA) would recommend that cows be removed from contaminated pasture. Cesium-137 was also detected in milk, but at concentrations expected from residual fallout from previous atmospheric weapons testing. No reactor-produced radioactivity has been found in any of the 377 food samples collected between March 29 and April 30 by the FDA.

Id. at 7 (emphasis added). The report concludes that the "predominant exposures to offsite individuals . . . [are] in the NNW [north-northwest], ENE [east-northeast], and SSE [south-southeast] sectors." Id. at 44. The east-northeast sector registered the highest cumulative dose — 83 mrem.[38] Id.

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38. According to the report, the south-southeast sector had a maximum cumulative dose of 41 mrem, and the north-northwest sector had a maximum cumulative dose of 37 mrem. Ad Hoc Group Report at 44-48.

Further, the report predicted the following with respect to potential health effects of the TMI accident:

> The projected total number of fatal cancers is less than 1 (0.7). The additional number of non-fatal cancers is also less than 1 (0.7). The additional number of genetic effects for all generations is also less than 1 (0.7). . . . All of these values are small compared to either the existing annual incidence of similar effects or the potential effects estimated to result from natural background radiation. . . . Comparing the total potential health impact of the accident with the estimated lifetime natural risk indicates that these effects, if they were to occur, would not be discernable. The uncertainties in the risk from low-level ionizing radiation would not alter this conclusion.

Id. at 60.

Next, Defendants point to the Report of the Task Group on Health Physics and Dosimetry of the President's Commission on the Three Mile Island Accident. The Commission's Task Group used available TLD data to estimate exposure levels for the areas surrounding TMI. The Commission concluded as follows:

> Persons within a 2-mile radius of the plant probably received the highest doses. The dose to the one person known to have been on one of the nearby islands, for about 9 1/2 hours during the first few days of the accident, is estimated to be

> about 50 millirems (mrem). In addition, about 260 people living mostly on the east bank of the river may each have received between 20 an 70 mrem. All other people probably received less than 20 mrem.

President's Commission, "Report of the Task Group on Health Physics and Dosimetry" at 16 (1979) (D-X-48) (hereinafter "Task Group Report"). In addition to calculating these short-range dose projections, the Task Group also used available plant data[39] to estimate a source term and determine

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39. The Task Group described the plant data relied upon as follows:

> The radiation monitor that was situated within the auxiliary building stack at TMI (which would have given the best estimate of the real-time releases) went off-scale at 8:00 a.m. on March 28, 1979. There was another gamma monitor located about 40 feet from the stack and less than 15 feet from the vent duct that "fed" the stack, which did not go off-scale. Careful graphical analysis of both the stack monitor (HPR-219) and the external gamma monitor (HPR-3236) strip charts showed that the count rate from both detectors rose from 7:00 a.m. to 7:45 a.m. on March 28, 1979, at approximately the same rate. The stack monitor was then used to calibrate the external gamma monitor, along with the known flow-rate in the stack; the integrated source term subsequently was calculated from the external gamma monitor readout. Due to several uncertainties, some of which cannot yet be quantified, the calibration value may be in error by as much as a factor of two. A check on this value was performed by looking at an air
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> (Cont'd)

maximum doses for a fifty mile radius surrounding TMI. Id. at 139-47. In terms of individual doses, the highest possible doses were assigned to those persons residing within a one-mile radius of the plant. Id. at 117. These persons were estimated to have been exposed to a maximum dose of 58.6 mrem. Id. Persons within a 5 to 10 mile radius of the plant had an estimated maximum dose of 5.2 mrem. Id. Finally, persons living within a 40 to 50 mile radius were estimated to have been exposed to a maximum dose of 0.28 mrem. Id.

The NRC also commissioned its own study of the TMI accident. See generally, Rogovin Report, supra. Following their extensive review of radiological and health-related conditions before, during and after the accident, see Rogovin Report, Vol. II, Part 2 at 341 (summarizing inquiry conducted and data relied upon), the NRC's Special Inquiry Group reached the following conclusion regarding releases during the TMI accident:

> There were numerous deficiencies related to radiation protection and radiological health; however, few, if any, of the deficiencies were causal factors in the TMI-2 accident. . . .

(Cont'd)

> sample (grab sample) that was obtained on March 31, 1979, between 12:00 noon and 2:00 p.m. from the stack itself, and comparing it to the external gamma monitor readout during this same time period. These two values were within 10 percent of each other, and thus sufficed as a means of confirming the calibration value of the external gamma monitor.

Task Group Report at 140.

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> The radiological consequences of the releases of radioactive material from TMI-2 into the environment are minimal at worst and may be nonexistent. Therefore, public concern regarding the effects of releases of radioactive materials from TMI-2 is not warranted.

Id. at 342. Noting that "[t]he buildings and equipment at the Three Mile Island Station provided substantial mitigation of the release of radioactive material to the environment," id. at 360, the NRC found that:

> the quantity of radioactive material . . . released in liquid effluents as a result of the accident is not significant . . . [and] the quantity of radioactive material released in gaseous effluents due to the accident consisted of 15 Ci of I[odine-131] and 2.4 million Ci of noble gases.

Id. at 362. In addition, the report found that although not perfect, the TLDs in place at the time of the accident were "adequate to characterize the radiation levels in the environment attributable to the accident." Id. at 395; see id. at 399, 407. With respect to its analysis of potential health effects related to the accident, the NRC reviewed existing governmental reports. Id. at 399. Indicating that "[t]he studies were independently performed with different methodologies, yet arrived at similar population dose estimates," id., the NRC "deemed it unnecessary to perform additional independent analysis of the raw data." Id. The NRC found the findings of both the Ad Hoc Group and the President's Commission Task Group to be accurate and verifiable. Id.

at 400. Based upon these findings, the NRC concluded that "the maximum offsite individual dose was less than 100 mrem."[40] Id. Finally, the report indicates that it is "extremely unlikely" that any individual will suffer future adverse health effects as a result of the accident. Id. at 408.

Next, Defendants direct the court's attention to a study commissioned by the Pennsylvania Department of Health (PADOH) in the wake of the TMI accident. Proceedings of the Pennsylvania Academy of Sciences, 57:99-102 (1983) (reporting the PADOH study) (D-X-1) (hereinafter "Proceedings"). In this study, PADOH performed dose assessments on each of the 34,000 members of the 13,000 households located within a five mile radius of TMI. Id. at 99. In June of 1979, a special census was conducted to identify the households included in the study. Id. at 100. "The TMI Population Registry resulting from the census effort has been estimated to be 95% complete." Id. Using a methodology similar to that used in TDR-TMI-116, id., the PADOH study estimated both maximum and likely dose estimates for a five mile radius around TMI. According to the study, the highest possible maximum dose was 165 mrem, and the highest likely dose was 80 mrem.[41] Id. at 101.

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40. Additionally, Defendants note that in determining that the TMI accident was not an extraordinary nuclear occurrence ("ENO"), the NRC determined that "the best estimate of actual maximum exposure was 'less than 70 or 80 mrem.' " (Defs.' Mem. in Supp. at 60 (quoting ENO Report App. E at 19).)

41. The study notes that due to the conservative methodology employed, the results were expected to overestimate actual doses by approximately forty percent. Proceedings at 101.

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The final study upon which Defendants rely in support of their case is a dose assessment study performed on behalf of the TMI Public Health Fund.[42] According to the authors, "[i]n the study reported in this paper, we tested a priori hypotheses that risks of specified cancers may have been raised by exposure to radiation emanating from the Three Mile Island nuclear power plant in Pennsylvania" during the TMI accident. Maureen C. Hatch, et al., "Cancer Near the Three Mile Island Nuclear Plant: Radiation Emissions," 132 Am.J. of Epidemiology 397, 397 (1990) (D-X-98) (hereinafter "Hatch"). The study used census data to divide a ten mile radius surrounding TMI into "study tracts." Id. at 399. For each of the study tracts, the authors analyzed yearly cancer rates for the years 1975 to 1985. Id. Incidence of cancer among the study subjects was determined through reference to the subjects' medical records obtained from local and referring hospitals.[43] Id. at 399-400. The authors assigned various cancers to respective study tracts based upon the place of residence of the patient at the time of diagnosis. Id. at 400. The study monitored cancer incidence with respect to Leukemia, cancer in children under 15 years of age, and "all cancers." Id. TMI plant data was used in conjunction with available meteorologic data to estimate releases and exposure during the accident. Id. at 401. Upon calculating their own release and exposure estimates, the Hatch study found the following:

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42. The TMI Public Health Fund was created through a settlement agreement which disposed of an earlier TMI-related class action suit. In accordance with the settlement agreement, the court has overseen the administration of the fund.

43. The study indicates that 99% of all records sought were obtained. Id. at 400.

> The fact that exposure patterns projected by the model and data from the thermoluminescent dosimeters [(TLDs)] compare so well indicates that available monitors were probably adequate to characterize accident releases. Thus, the comparison provides a justification for using official exposure estimates as "best estimates" of the level of radiation corresponding to points along our relative scale.

Id. at 402. The overall findings of the study were summarized by the authors as follows:

> In summary, the possibility that emissions from the Three Mile Island nuclear power plant could have contributed to the observed trends, in lung cancer particularly, must be weighed against 1) the lack of effects on the cancers believed to be most radiosensitive and the indeterminate effects on children; 2) the threat of confounding by factors unmeasured or inadequately controlled; 3) inconsistency within our own data between the findings for plant emissions and background gamma radiation; and 4) the low estimates of radiation exposure and the brief interval since exposure occurred. Pending a demonstration that very low-dose gamma radiation can act as a tumor promoter or the identification of another late-stage carcinogen in the effluent stream, an effect of plant emissions in producing the unusual patterns of lung cancer and non-Hodgkin's lymphoma appears unlikely, and alternative explanations

> need to be considered. The increased risk that we observed for childhood cancers in relation to routine emissions is compatible with increases reported near some other nuclear installations, but confidence intervals are wide and, for leukemia, the numbers are small and the rates found in the Three Mile Island area low compared with national and regional data.

Hatch at 410-11 (emphasis added). Accordingly, Defendants contend that this study supports their theory that dangerous levels of radiation did not reach populated areas; and, as such, no adverse future health effects can reasonably be expected to have occurred.

In addition to the plethora of studies conducted in the wake of the accident, Defendants contend that there exists a significant body of biodosimetric data, collected through environmental monitoring, which tends to corroborate the ultimate conclusions of the many studies. This data includes measurements of on and off-site TLDs, and samples of air, water, milk, food, soil, vegetation and animals. (Defs.' Mem. in Supp. at 69.) The data was collected by a variety of different sources. For example, Defendants note that Metropolitan Edison's REMP, which surpassed NRC guidelines as to its extensiveness prior to the accident, was augmented during the accident to increase the breadth of the sampling program. Additionally, Defendants highlight that the Commonwealth of Pennsylvania, the NRC, the HEW, the EPA, and the DOE each also engaged in their own sampling programs in response to the accident in an attempt to gauge accident effects.

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The most extensive human accident data is that collected through the NRC's whole body count program, and through thyroid scans performed at area hospitals. See NUREG-0636, The Public Whole Body Counting Program Following the Three Mile Island Accident (1989) (D-X-35). The NRC took whole body counts of TMI area residents between April 10 and April 18, 1979. Based upon the whole body count results, the NRC determined that "no radioactivity was detected which could have originated from Unit-2 releases." Id. at 11. Although no such doses were detected through their study, the NRC determined that "the maximum (undetectable) dose to a typical thyroid could have been about 12 millirem." Id. Such a dose would have been approximately 12% greater than the average background dose received annually by Pennsylvania residents. Id. Hershey Medical Center and York Hospital both provided thyroid scans for a limited number of local residents.[44] The thyroid scans revealed no evidence of exposure to iodine or other fission products. The 148 urinalyses performed by HEW were similarly unremarkable.

In sum, Defendants argue that all of the reports and data related to the TMI accident confirm that area residents, if exposed at all, were exposed to less than 100 mrem of radiation during the accident. (Defs.' Mem. in Supp. at 79.)

2. Health Effects

Defendants contend that "no significant health effects from the accident were predicted to occur and . . . none have

44. Hershey Medical Center scanned 117 individuals, and York Hospital scanned 41 individuals. (1/21/93 Porter Affidavit at ¶¶ 17-18.)

been observed." (Defs.' Mem. in Supp. at 80.) In support of their argument, Defendants point to the same federal and state government reports referred to by the court in the preceding discussion. Specifically, Defendants note that the Ad Hoc Group predicted that less than one additional fatal cancer would occur in the population within 50 miles of the plant over the course of its lifetime, Ad Hoc Group Report at 61; that the President's Commission Task Group on Radiation Health Effects found that

> The projected number of fatal cancers or nonfatal cancers potentially induced or temporally advanced over the remaining lifetime off-site population within 50 miles of the TMI plant site from whole-body gamma radiation exposure is less than one, and the total number less than 1.5, with zero or near-zero not excluded[,]

President's Commission Report at 202; and, that the NRC Special Inquiry Group found the increased risk of developing fatal cancer as a result of the TMI incident to be approximately 1 in 100,000, while the risk of developing fatal cancer from all other sources during a lifetime was approximately one in seven, Rogovin Report at 153.

According to Defendants, the epidemiologic evidence confirms that the early estimates regarding probable health effects are correct. The PADOH has conducted epidemiological studies concerning pregnancy outcomes and cancer mortality, neither of which have produced remarkable findings. See generally, J.R. Bratz, et al., Three Mile Island (TMI) Pregnancy Outcome Study — Final Report at 4. (1988)

(D-X-2) (finding that the "impact of the TMI nuclear accident upon pregnancy outcome was negligible, if any"); E. Digon, et al., Infant, Fetal Neonatal and Perinatal Mortalities in the Three Mile Island Area (1988) (D-X-3) (study of pregnancy outcomes finding that "the levels of post-TMI fetal, neonatal, perinatal or infant mortalities in the vicinity of the TMI nuclear facility were neither significantly higher than expected nor significantly different from the pre-TMI years. There is no clear evidence that the 1979 nuclear accident impacted significantly on the risk of late in-utero mortality or mortality during infancy. . . ."); PADOH, Cancer Mortality and Morbidity (Incidence) Around TMI at 23, 24 (1985) (D-X-13) (finding no "evidence of increased cancer risks to residents near the TMI nuclear facility"); K. Ramaswamy, et al., Three Mile Island (TMI) Population Registry-Based Cohort Mortality: 1979-1985 Period at 17-18 (1988) (D-X-6) (finding that "[n]ormal mortality experiences and life expectancy of the TMI cohort, as observed at this time, seem to be consistent with the very low level of ionizing radiation released during the TMI accident[,]" and noting that observed limitations on study design should not significantly impact the findings); G.K. Tokuhata, TMI Population Registry Based Cohort Cancer Incidence July 1982-June 1989 at 6 (1991) (D-X-15) (concluding that "[t]he analyses provided no evidence that the 1979 nuclear accident has had a significant impact upon the overall incidence of cancer observed during the 7-year follow-up period beginning in 1982").

Finally, Defendants have presented evidence that there were no increases in hospital utilization between June of 1978 and June of 1993 that can be attributed to the TMI accident.

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See generally Larry Fosselman, A Look at Hospital Utilization Relative to Three Mile Island at 3 (July 14, 1995) (D- X-7) ("There are no deviations in the hospital utilization data that can be attributed to the March 28, 1979, Three Mile Island Accident.") Fosselman's study was based on the hypothesis that if populated areas were exposed to significant levels of radiation, there would have been a notable increase in the local demand for health services.

In sum, Defendants have presented extensive evidence documenting their position that dangerous levels of radiation did not reach populated areas during the TMI accident. The evidence includes a source term; analyses of release pathways; plume dispersion analyses; general and epidemiological studies examining potential health effects of the accident and finding no significant effects; and, a multitude of governmental reports examining the causes and effects of the TMI accident.

B. The Plaintiffs' Case

1. Exposure/Dose Evidence

Plaintiffs' case is premised upon the theory that one or more hydrogen "blowouts" occurred during the TMI accident, whereby large quantities of radioactive noble gases were expelled into the environment. Following this blowout, Plaintiffs contend that a dense yet narrow plume of radioactive noble gases (from the blowout) traveled through the atmosphere, evading the TLDs in the TMI REMP, and exposing Plaintiffs to high levels of radiation. The blowout is important to Plaintiffs' theory of the case because it

purports to explain how quantities of radiation higher than those estimated by Defendants were expelled into the atmosphere. The report of David Lochbaum[45] is offered as Plaintiffs' source term expert to support their blowout theory.

Through his report, Lochbaum sought "to evaluate the role of the letdown line[46] as a release pathway for noble gases." (3/5/96 Tr. at 1427 (footnote added).) Lochbaum examined plant data, published reports regarding the accident, and the reports of Defense experts Akers and Daniels in reaching his conclusions. His methodology entailed defining "the conditions that had to be satisfied in order for a letdown line blowout to have occurred, and then determin[ing] when, if ever, during the accident, those four conditions were met." (Id.) Lochbaum characterizes the blowout conditions as follows:

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45. Lochbaum has a bachelor's degree in nuclear engineering and seventeen years of experience in the nuclear power industry. He is not Plaintiffs' original source term expert. The court permitted Lochbaum to submit an expert report, to be reviewed at the court's second round of Daubert hearings, when Plaintiffs' expert Richard Webb suddenly recanted his proffered source term testimony at the conclusion of the first round of Daubert hearings. In re TMI Litigation Cases Consolidated II, 911 F.Supp. 775, 788-91 (M.D.Pa.1996).

46. "Following a reactor shutdown, as the reactor coolant pressure drops and the reactor coolant expands, some reactor coolant must be removed from the system in order to allow depressurization to continue. The letdown line serves this purpose in a reactor trip situation." (4/28/93 Daniel Report at 33.)

> (1) the letdown line must be in operation, (2) both reactor coolant pumps in the RCS loop A must not have been in operation, (3) natural circulation through RCS loop A must not have been occurring, and (4) the connection of the letdown line to the 1A cold leg must not have been covered with water.

(1/22/96 Lochbaum Rpt. at 3; see also 3/5/96 Tr. at 1427.) In his report, Lochbaum concludes that "[t]he four prerequisites for a potential 'blowout' through the letdown line may have been satisfied on three occasions during the first day of the TMI-2 accident, but the indications do not conclusively point to any 'blowout. . . .' " (1/19/96 Lochbaum Rpt. at 14 (emphasis added).) When summarizing plant monitor responses that indicated a possible blowout, Lochbaum noted that the "evaluation does not claim that both of these discussions apply to the TMI-2 accident. But it is credible that one of these radiation monitor responses could have been caused by a blowout." (Id. at 10.) At the Daubert hearings, Lochbaum stated his findings with further equivocality. "I looked at a number of system parameters to try to determine whether a blowout may have occurred . . . or evidence that would have shown that a blowout could not have occurred . . . [a]nd for each of the periods . . . there were radiation indications that would have supported a blowout . . . and there were other indications that showed that it was unlikely a blowout occurred." (3/5/96 Tr. at 1446.) Lochbaum further testified that he did "not believe there was evidence of a blowout. . . . but if a blowout occurred, its duration was of limited length. . . . A short duration blowout would still have been significant because of the high gas,

concentrated gas transport that would have occurred. . . . But I did not see conclusive evidence of a blowout." (Id. at 1455-56 (emphasis added).)

Despite finding no evidence of a blowout through the letdown line, Lochbaum concludes that there "was clearly a 'blowout' of noble gases through steam generator B in the early hours of the accident." (1/22/96 Lochbaum Rpt. at 18.) Additionally, Lochbaum finds that there were several "unfiltered release[s] of noble gases" into the atmosphere during the accident. (Id. at 18.) The court notes that Defendants' expert Daniel also points to these pathways of release in explaining his release estimates. Based upon this, Lochbaum opines that "it is concluded with reasonable scientific certainty that significantly more than 10 million curies of noble gases were released into the atmosphere." (Id. at 20.) Lochbaum does not explain what radionuclides were released or the quantities of each that were released. His opinion of the overall quantity of release appears to be based upon his assumption that "[d]ue to limited sampling and monitoring on the day of the accident, a sizeable quantity of short-lived noble gases could have been released to the atmosphere during a 'blowout' or via the other release mechanisms instead of simply decaying away." (Id. at 19.)

Next, Plaintiffs rely upon the testimony of Ignaz Vergeiner to support their contention that following the alleged blowout, a narrow yet highly concentrated plume of radiation was carried to locations where Plaintiffs resided. Dr. Vergeiner was offered to testify regarding plume dispersion and to give quantified dose estimates based upon the path taken by the plume. A significant portion of

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Dr. Vergeiner's proffered testimony was found to be inadmissible during the Daubert hearings based upon the unscientific and unreliable methodology supporting his testimony. See In re TMI, 911 F.Supp. at 791-99 (M.D.Pa.1996) (finding dose estimates, "plume movie"[47] and water model to be inadmissible). The court did, however, find Dr. Vergeiner's testimony regarding "weather conditions during and immediately following the accident" to be admissible. Id. at 799. The Daubert ruling also directed Plaintiffs to provide an offer of proof explaining "how this narrow area of testimony 'fits' absent Dr. Vergeiner's other proposed testimony." Id. While not expressly providing an offer of proof, Plaintiffs have framed Dr. Vergeiner's testimony as follows:

> Dr. Vergeiner will opine that the meteorological conditions existing at the time of the accident, combined with the alpine terrain (i.e., hilly or mountainous) which exists near the TMI facility, combined to keep the radioactive plume released during the TMI accident from rising and dispersing high into the atmosphere. According to Dr. Vergeiner, radioactive plumes remained narrow, intense and intact, and moved in an erratic fashion towards the areas located north/northwest

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47. The "plume movie" consisted of a series of hand-drawn sketches which Dr. Vergeiner "eyeballed," and which purported to be a visual representation of the plume dispersion analysis made by Dr. Vergeiner. See, e.g., Pomella v. Regency Coach Lines, Ltd., 899 F.Supp. 335, 343 (E.D.Mich.1995) (finding methodology of "eyeballing" the coefficient of friction related to highway pavement under varying weather conditions to be scientifically unreliable).

> of the TMI facility, coming frequently into contact with the hilly and semi-mountainous terrain of that area.

(Pls.' Ans. and Mem. in Response to Defs.' Motn. for Summary Judgment at 44 (hereinafter "Pls.' Op. Brief").) In their reply brief, Defendants argue that this characterization of Dr. Vergeiner's testimony flies directly in the face of the court's in limine ruling. To an extent, Defendants are correct. Implicit in the court's ruling that Dr. Vergeiner's "plume movie" was scientifically unreliable, was the finding that the methodology employed in deriving the plume movie was unreliable. Thus, it defies logic to presume that Dr. Vergeiner could verbally testify, based upon the same methodology, to the very opinions that the court refused to allow Dr. Vergeiner to present through his plume movie. Defendants are, however, mistaken to suggest that this court's ruling precludes Dr. Vergeiner from testifying as to basic meteorological concepts and prevailing weather conditions during the accident. Dr. Vergeiner is permitted to testify to the prevailing weather conditions during the accident, and to how these conditions impacted plume dispersion. He is not permitted to give quantified dose estimates, discuss his "plume movie" or demonstrate his water model.

To provide evidence of exposure and dose, Plaintiffs rely on the testimony of Steven Wing and Vladimir Shevchenko. Dr. Steven Wing, who holds a Ph.D in epidemiology and is currently a Professor of epidemiology at the University of North Carolina at Chapel Hill, has performed a reanalysis of

the Hatch cancer incidence study.[48] (2/25/95 Report of Steven Wing (hereinafter "2/25/95 Wing Report").) The Hatch study found no evidence of an increase in cancer incidence following the TMI accident that could be attributed to the accident. According to Plaintiffs, Dr. Wing undertook his reanalysis based upon his belief that "the Susser/Hatch study contained an a priori hypothesis that doses from the TMI accident were too low to affect cancer rates." (Pls.' Op. Brief at 54.) Dr. Wing explains the possible effect of this hypothesis as follows:

> The fact that positive associations were not interpreted as giving support to the a priori hypotheses suggests strongly that the authors were unwilling to consider rejection of the null hypothesis based on evidence from their analyses, a position consistent with the view that exposures were too low to have produced any measurable changes in cancer incidence.
>
> An unwillingness to consider positive findings as evidence in support of a priori hypotheses may have influenced not only interpretations of planned analyses but also the extent of exploration of other analyses that might have been sensitive under alternative assumptions. First, if the authors

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48. Hatch et al. performed a cancer incidence study on the TMI area to determine whether the accident caused an increase in cancer incidence. Maureen Hatch, et al., "Cancer Near the Three Mile Island Nuclear Plant: Radiation Emissions," 132 Am.J. of Epidemiology 397 (1990). The study was undertaken on a grant from the TMI Public Health Fund.

had considered the possibility that exposures had been grossly underestimated, positive results could have been considered not only as an indication of possible confounding, but also as an indication of a possible accident effect. The failure to consider this possibility may be due, in part, to the conditions under which the dose reconstruction for this study was performed, which stipulated that, "The principal investigator shall not attempt to make upper limit or worst case estimates of releases of radioactivity or population doses." Second, the authors might have considered (but did not discuss) the potential for misclassification of relative doses, incomplete case ascertainment, use of residence at time of diagnosis rather than at time of accident, and lack of control for confounding factors, as problems that could lead to underestimation of measures of effect.

(2/25/95 Wing Report at 3 (internal citation omitted).) Dr. Wing believes that an "ongoing collection of evidence [is] suggestive of high level radiation exposure in the pathways of radioactive gas plumes." (Id.) His report reveals that this body of evidence consists of: statements from "[m]onitoring stations in Albany, NY and Portland, ME [that they] detected radioactive gas plumes at times and during weather conditions which indicated that their source was the TMI accident"; evidence of morphological damage in trees in the TMI area that is consistent with radiation exposure, see infra at 861-862 (explaining the Shevchenko tree study); and interviews with area residents conducted by Plaintiffs'

consultants, the Aamodts, in which the residents provide anecdotal accounts of "reddening of the skin, hair loss, vomiting, metallic taste, and pet deaths" at the time of the accident. (2/25/96 Wing Report at 4.)

Using the same data as Hatch, but employing a slightly different methodology,[49] Dr. Wing performed a reanalysis of the data. The Wing study compared pre-accident associations between radiation exposure and cancer to post-accident associations between the same factors. (Id. at 10.) Significantly, the study presumed high levels of radiation exposure. (2/25/95 Wing Report at 9 ("Unlike the original reports based on these data, our re-analyses assumed that absolute accident doses could have been large enough to produce measurable impacts on cancer incidence through some combination of promotion, immune system and initiation mechanisms.") The study resulted in a finding that "[a]nalyses of the post-accident change in association of the accident dose and cancer incidence showed no instances of diminution of association[,]" and showed the greatest

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49. In his 10/19/95 affidavit, Dr. Wing explains the methodological alteration as follows:

> [the] primary method used by Hatch et al. (1990) was to use socioeconomic variables to control for base line incidence in the analysis of potential accident impact. In our alternative approach, we adjust for the base line (pre-accident) association between cancer incidence and accident dose analyses of the accident effects.

(10/19/95 Aff. of Steven Wing at 4.)

association for leukemia.[50] (Id. at 9.) Based upon this finding, Wing concludes that "[t]he increases in cancer incidence related to estimated radiation doses from the TMI accident are consistent with allegations that the magnitude of radiation exposures from the accident were much higher than has been assumed in past studies." (Id. at 11.) Plaintiffs argue that the Wing reanalysis, standing alone, creates a material factual dispute as to the issue of dose.

Plaintiffs' final "dose" expert[51] is Vladimir Shevchenko. Professor Shevchenko has vast experience in studying the

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50. Dr. Wing notes that the strong association with leukemia "might be expected based on previous studies showing a higher radiosensitivity of leukemia than solid tumors. . . . [and] may also reflect, in part, a shorter latency for this cancer." Id. at 9.

51. Plaintiffs have also placed on the record a sealed exhibit (P-X-92) and sealed testimony from the Daubert hearings (2/16/96 Tr. at 724-29 (testimony of Bruce Molholt)), purporting to show high levels of iodine in milk samples taken on March 30, 1979. According to the testimony, several of the sixty-eight samples taken on that date contained high levels of iodine. (2/16/96 T. at 725-26.) One sample contained very high levels of iodine. The exhibit, however, does not explain where any of the milk samples were taken from. The samples are coded, and Plaintiffs have not produced the key to the code. Dr. Molholt testified that the sample with the highest level of iodine came from a farm near Mechanicsburg. (Id. at 726.) When asked how he knew this without knowing the codes used in conjunction with the samples, he explained that he was told by reliable source. (Id. at 728.) That source was revealed to be Plaintiffs' consultant, Norman Aamodt. Plaintiffs have placed no admissible evidence on the record which explains where each of the samples were taken from. As such, this evidence fails to create a material factual dispute as to the issue of dose.

effects of ionizing radiation in the former Soviet Union. As the court noted in its first Daubert ruling:

> Professor Shevchenko holds a Ph.D in Biological sciences, and has particular expertise in the area of radiation genetics; specifically with respect to the cellular and subcellular effects of radiation on plants. Much of this expertise has been developed through his practical experience studying radiation effects in the Eastern Ural Radiation Belt region, at the site of the Kyshtym atomic weapons plant accident, at the site of the Chernobyl nuclear power plant accident, at the Semipalatinsk Polygon, and at the sites of nuclear experiments in the Alti Region.

In re TMI, 911 F.Supp. at 810 (internal citations omitted). Plaintiffs offered Professor Shevchenko to testify as to the results of a tree study he performed in the TMI area, and as to the results of cytogenetic analyses performed upon blood samples of TMI area residents.

The Shevchenko tree study concluded that trees in the TMI area exhibited morphological changes that could only be caused by radiation exposure. To conduct his study Professor Shevchenko traveled to the United States and viewed certain trees in the TMI area. In re TMI, 911 F.Supp. at 811. In his deposition, Professor Shevchenko indicated that he was directed to the locations of some of the damaged trees by Plaintiffs' expert James Gunckel and by Plaintiffs' consultant Norman Aamodt; and, that he selected some of the study trees on his own. (Shevchenko Dep. at 62-67.) It is

alleged that the trees selected were in the path of the TMI plume. The methodology utilized by Professor Shevchenko in conducting his tree study has been described as follows:

> The methodology consisted of visual observation of trees in the TMI area, comparing the types and kinds of damages of the trees in the TMI area to trees observed in Chernobyl and damages in the gamma fields and making a professional judgment as to whether the damages and effects manifested by the trees in the TMI area reflected radiation exposure and dose within a specific range.

In re TMI, 911 F.Supp. at 811. Based merely upon his observations, Professor Shevchenko was prepared to make quantified dose estimates as to the levels of exposure necessary to cause the damage exhibited. Id. Ultimately, the court found Professor Shevchenko's general observations and comments regarding tree damage to be admissible, and found his quantified dose estimates to be inadmissible. In re TMI, 922 F.Supp. at 1013-15. Accordingly, Professor Shevchenko will testify to the similarities he observed between the study trees in the TMI area and radiation exposed trees he has observed in the former Soviet Union.

Professor Shevchenko was also offered to testify as to a cytogenetic analysis performed on the blood samples of 29 TMI area residents. In conducting this analysis, blood samples are viewed under a microscope to determine whether dicentric chromosomes are present. Dicentric chromosomes are chromosomes that have two centromeres rather than one, and they are a biomarker of radiation exposure. That is, the

presence of elevated numbers of dicentric chromosomes provides biological evidence of a past radiation exposure. Because dicentric chromosomes disappear rapidly over time, cytogenetic analysis is most useful when conducted immediately following exposure. A method, known as the "FISH (fluorescence in situ hybridization) technique," has recently been developed to accurately detect chromosome aberrations (i.e. dicentrics) when longer periods of time have elapsed since exposure. See In re TMI, 922 F.Supp. at 1011-12, for a more detailed discussion of the FISH technique.

In the summer of 1994 and winter of 1995, blood samples of TMI area residents were collected for the Shevchenko study. The samples were transported to the former Soviet Union, and a cytogenetic analysis was performed for Professor Shevchenko by Dr. Snigiryova. The analysis revealed that four of the blood samples contained elevated levels of dicentric chromosomes.[52] Based upon this observation, Professor Shevchenko was prepared to give a quantitative dose estimate as to the level of radiation that these persons must have been exposed to in order to exhibit

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52. Professor Shevchenko bases his conclusion that there are elevated levels of dicentric chromosomes on his comparison of the TMI blood samples with a Russian control group. Defendants argue that this is an inaccurate comparison because natural levels of background radiation differ significantly worldwide. Accordingly, what may be a "normal" level of chromosome aberrations for a resident of the TMI level may be an "abnormally high" level of aberrations for a resident of the former Soviet Union, or vice versa. Viewing the facts in a light most favorable to Plaintiffs, the court will presume that the Russian controls were adequate.

the demonstrated levels of dicentric chromosomes. As with the tree study, the court found the general cytogenetic testimony and study findings to be admissible, and the quantified dose estimates to be inadmissible. Consequently, Professor Shevchenko will offer general testimony regarding the use of dicentric chromosomes as a biomarker of radiation exposure, and more specific testimony regarding the results of the cytogenetic analysis performed on the TMI area blood samples. Professor Shevchenko will not be permitted to give quantified dose estimates. In re TMI, 922 F.Supp. at 1012-14.

Plaintiffs contend that their admissible evidence supports their theory that dangerous levels of radiation reached populated areas during the TMI accident, and that summary judgment is therefore, inappropriate.

2. Medical Causation Evidence

Plaintiffs rely upon four principal witnesses for their medical causation case: Dr. Louis Fajardo, Dr. Thomas Winters, Dr. Jose Galindo and Dr. Joseph Cardinale. The court has found the testimony of these experts to be admissible provided that Plaintiffs offer dose evidence sufficient to support the levels of exposure that each of these experts presumed in offering their opinions. In re TMI Litigation Cases Consolidated II, 166 F.R.D. 8, 10 (M.D.Pa.1996) (discussing Galindo and Cardinale); id., 922 F.Supp. at 1044-45 & nn. 6-7, 12-14 (discussing Winters, Fajardo and Galindo); id., 922 F.Supp. at 1031-37 (discussing Fajardo). The court will assume arguendo for the purpose of this discussion that Plaintiffs have proffered sufficient dose evidence.

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Based upon a review of test Plaintiffs' medical records and use of the differential diagnosis methodology, Dr. Louis Fajardo will testify that eight of the test Plaintiffs' neoplasms are causally related to exposure to ionizing radiation during the TMI accident.[53] Dr. Fajardo's opinion is premised upon an understanding that other testimony will support the contentions that Plaintiffs were exposed to at least 10 rems of radiation, and that there was an observable increase in cancer incidence in the TMI area following the accident. See In re TMI, 922 F.Supp. at 1030-31. Dr. Winters will offer similar testimony based upon his review of medical records, his examination of the still-living test Plaintiffs and his use of a differential diagnosis methodology. As with Plaintiffs' other medical causation experts, Dr. Winters presumed a significant exposure when reaching his conclusions. In re TMI, 922 F.Supp. at 1042-43 ("[I] knew the dose was above a hundred rems, and figured that even if it dropped down to the 50- or 10-rem area, [my] . . . opinion would still be the same.") However, Dr. Winters will offer his opinion that all ten of the test Plaintiffs developed their respective neoplasms as a result of exposure to radiation during the TMI accident.

Finally, Drs. Galindo and Cardinale, treating physicians of test Plaintiff Lori Dolan, will testify as to the suspected etiology of her neoplasm. Both physicians will offer their opinion that it is more likely than not that Plaintiff Dolan's thyroid cancer resulted from exposure to radiation during the TMI accident. Both doctors base their opinions upon Plaintiff Dolan's and counsel's representations that Plaintiff

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53. The eight test Plaintiffs are Paula Obercash, Gary Villella, Leo Beam, Joseph Gaughan, Lori Dolan, Jolene Peterson, Pearl Hickernell, Ethelda Hilt and Ronald Ward.

Dolan was exposed to high levels of radiation during the TMI accident. In re TMI, 922 F.Supp. at 1054 (Cardinale); 166 F.R.D. at 10 (Galindo). Moreover, both doctors expressly note that they depend upon other experts to quantify the exact level of exposure received by Plaintiff Dolan. Id., 922 F.Supp. at 1053-54 (Cardinale); 166 F.R.D. at 9 (Galindo). The treating physicians of other of the test Plaintiffs have not been identified as expert witnesses. Plaintiffs contend that their dose and causation evidence is sufficient to create material factual disputes regarding the amount and effect of radiation released during the accident.

One final point regarding Plaintiffs' expert testimony bears noting. It appears that virtually all of Plaintiffs' dose experts were directed to presume a dose in excess of 100 rems when formulating their opinions. Further, it seems that each of the experts was assured that some other expert (or experts) would establish that this high dose level was plausible. The court surmises that Plaintiffs' strategy was to layer and intertwine all of their expert testimony to effectively produce one super-expert opinion. Had each of Plaintiffs' experts produced the results they were expected to produce, this strategy may have proven to be highly effective. However, the expert providing the crucial opinion — that demonstrating radionuclide releases high enough to support the presumed 100 rem dose — recanted the bulk his opinions in an unsolicited voicemail message left with counsel for Defendants. In re TMI, 911 F.Supp. at 790 ("I don't get the high releases that I got before. . . . There's no blowout."). Plaintiffs necessarily withdrew this expert's report, and subsequently failed to produce other testimony supporting the 100 rem assumption. As such, the record

evidence no longer supports any expert opinion that is expressly premised upon the belief that Plaintiffs were exposed to high levels of ionizing radiation.

In sum, Plaintiffs' case rests upon the following evidence: the Lochbaum testimony that a blowout may or may not have occurred, and that if one did occur, more than 10 million curies of noble gases were released from the plant during the accident; Dr. Vergeiner's testimony regarding how prevailing weather conditions may have effected plume dispersion and travel during the accident; Dr. Wing's cancer incidence study; and Professor Shevchenko's cytogenetic analysis and tree study.

C. Plaintiffs' Burden of Proof

Although this court has original federal question jurisdiction over the captioned action, Pennsylvania tort law controls with respect to Plaintiffs' burden of proof. 42 U.S.C. § 2014(hh) (1988). The Third Circuit has held that to succeed on their claims, Plaintiffs must show that:

> 1) defendants released radiation into the environment in excess of the §§ 20.105 or 20.106 levels; 2) plaintiffs were exposed to this radiation (although not necessarily at the levels prohibited by §§ 20.105 and 20.106); 3) plaintiffs have injuries; and 4) radiation was the cause of those injuries.

In re TMI, 67 F.3d at 1119 (hereinafter "TMI analysis"). The Third Circuit also has held that the Pennsylvania rule

that medical experts must testify to their conclusions with a "reasonable degree of medical certainty" is an element of the plaintiff's burden of proof in toxic tort cases. In re Paoli Railroad Yard PCB Litigation, 35 F.3d 717, 751-52 (3d Cir.1994) (citing Cohen v. Albert Einstein Medical Ctr., 405 Pa.Super. 392, 592 A.2d 720, 724 (1991), appeal denied, 529 Pa. 644, 602 A.2d 855 (1992)) ("the Cohen court strongly implied that, even if admissible, testimony with less than a reasonable degree of medical certainty was insufficient to prove causation") (hereinafter "Paoli II").

Defendants have conceded factor 1, and factor 3 is not disputed by the parties. It is factors 2 and 4 that present the greatest challenges in this litigation. Another district court faced with similar issues noted as follows:

> Because cancers are synergistic the evaluation of different risk factors is an inherently complicated endeavor. The examination of a malignancy, for example, will not reveal the cause of the cancer in question. Thus, determining whether exposure to ionizing radiation contributed to causation of cancer is extremely complex. The record reflects that making such a determination requires consideration of numerous factors, including the circumstances of exposure; the amount and rate of radiation exposure; the type of radiation received (gamma, beta, alpha, neutron, low LET and high LET); the pathways of radiation exposure; the duration of exposure; the age at manifestation of the disease; the nature of the . . . disease; the effects of other risk factors and of

> exposure to other carcinogenic agents; the medical history of the [Plaintiff] . . .; the latency period between exposure and disease manifestation; the [Plaintiff's] . . . health at the time of exposure; the [Plaintiff's] . . . gender; and whether the [Plaintiff] . . . manifested acute symptoms of radiation exposure just after exposure.

National Ass'n of Radiation Survivors v. Derwinski, 782 F.Supp. 1392, 1398 (N.D.Cal.1992); see O'Conner v. Commonwealth Edison Co., 807 F.Supp. 1376, 1382 (C.D.Ill.1992) ("Radiation exposure and its effects upon humans is a very complex subject.").

In explaining the "exposure" element of Plaintiffs' burden, the Third Circuit stated that Plaintiffs must show that they "were exposed to this radiation (although not necessarily at the levels prohibited by [10 C.F.R.] §§ 20.105 and 20.106)." In re TMI, 67 F.3d at 1119. The lowest level prohibited by sections 20.105 and 20.106 is 0.5 rems (500 mrem).[54] Standing alone, the court interprets this element to mean that Plaintiffs must show exposure to any amount of radiation from TMI — even if that amount is less than

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54. Section 20.105 mandates, among other things, that an NRC licensee's application be approved where that licensee demonstrates that operation of the facility is not likely to cause anyone offsite to be exposed to in excess of 0.5 rems (500 mrem) of radiation annually. 10 C.F.R. § 20.105. Section 20.106 states that a licensee "shall not possess, use, or transfer licensed material so as to release to an unrestricted area radioactive material in concentrations which exceed the limits specified in Appendix 'B', Table II of this part, except as authorized." 10 C.F.R. § 20.106.

.5 rems. However, the Third Circuit also noted that "[t]his 'exposure' element requires that plaintiffs demonstrate they have been exposed 'to a greater extent than anyone else,' i.e. that their 'exposure level exceeds the normal background level.' " In re TMI, 67 F.3d at 1119.

Presuming that Plaintiffs can show that they were exposed to radiation emitted during the TMI accident, the issue becomes whether they can also demonstrate that the exposure was more likely than not the cause of their respective neoplasms. It is with consideration of this factor that the court's analysis collides with gray areas of science and produces a complicating morass of legal rules and scientific theory. There appear to be two types of evidence with which Plaintiffs may show causation: direct evidence of the actual quantity of their radiation exposure, and indirect evidence which suggests that the exposure, even if it cannot be quantified, caused their neoplasms.

With respect to the quantity of radiation exposure, there is a consensus within the relevant international scientific community that exposure to high levels of ionizing radiation (in excess of 100 rems) will induce cancer. See supra at 843, 844-845. That being said, the same scientific community will also agree that: 1) it is impossible to determine the precise etiology of a given cancerous tumor; and 2) at doses below 10 rems, the causal link between radiation exposure and cancer induction is entirely speculative. Id. This raises the problem of precisely how many rems of radiation exposure suffice to meet the "more likely than not" standard? Is it possible for something that is "speculative" for scientific purposes to be "more likely than not" for legal purposes?

That is, can Plaintiffs meet their burden of proof if the evidence supports the inference that they were exposed to not more than 9 rems of ionizing radiation (e.g. where scientist would say the causal link was speculative)?

After careful review of the extensive scientific record in this case, the court finds that to the extent Plaintiffs seek to establish causation on the basis of a specific radiation exposure level, they must present evidence based upon which a fact finder could reasonably infer that each Plaintiff was exposed to 10 rems or more of ionizing radiation during the TMI accident.[55] If the most eminent scientists in the world

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55. In Johnston, the court alluded to the difficulty presented when the relevant scientific community can only hypothesize about the causal relationship between a toxic exposure and subsequent health effects:

> The radiation protection community scientists who have gathered this data for more than half a century have concluded that scientifically observable excess numbers of cancer have appeared in populations exposed to high doses of radiation. These high doses are generally above approximately 100 rem. Since the highest dose that any of these four plaintiffs received is only 3.2 rem, we have no reliable data that gives us excess cancers for such a low level of exposure. The way radiation scientists estimate the risks at low doses is to use various hypotheses such as the linear hypothesis or the quadratic hypotheses or the linear-quadratic hypothesis. This court finds that when radiation scientists speak about a mathematical risk from a 3.2 rem dose of radiation, they are speaking about "theoretical, hypothetical numbers." These types of numbers are not real numbers because if that risk exists at all it is "not something you can determine in a quantitative fashion in real life."

Johnston, 597 F.Supp. at 423 (internal citations omitted).

are unwilling to do more than speculate as to the causal link between radiation exposure and cancer induction at doses below 10 rems, no rational jury, confronted with identical evidence, could find it more likely than not that radiation induced a given neoplasm. Johnston, 597 F.Supp. at 425 ("Cause in tort law needs to be founded on more than a theory or hypothesis."); id. at 426 ("when the doses are so low that the existence of any effect at all is only hypothetical theory, such calculations are mere speculation. . . . [and] these calculations should not, nor will they, be accepted here as valid evidence on causation"); accord Paoli II, 35 F.3d at 766 (noting that even if doctor's testimony had not been excluded as scientifically unreliable, it "did not have sufficient scientific certainty to survive summary judgment"); Turpin v. Merrell Dow Pharmaceuticals, Inc., 959 F.2d 1349, 1360-61 (6th Cir.1992) ("The analytical gap between the evidence presented and the inferences to be drawn on the ultimate issue . . . is too wide. Under such circumstances, a jury should not be asked to speculate on the issue of causation."). Although not binding authority, the court also finds Merrell Dow Pharmaceuticals, Inc. v. Havner, 907 S.W.2d 535, 541 (Tex.Ct.App.1994), to provide persuasive authority:

> To establish proof, the expert testimony must establish the "reasonable probability" of a causal connection. . . . [T]his probability must, in equity and justice, be more than coincidence before there can be deemed sufficient proof for the Plaintiff to go to the jury. . . . In the absence of reasonable probability, the inference of causation amounts to no more than conjecture or speculation. . . . [A]

> possible cause only becomes "probable" when in the absence of other reasonable causal explanations it becomes more likely than not that the injury was a result of its action. This is the outer limit of inference upon which an issue can be submitted to the jury.

Id. According to the Havner court, expert scientific testimony "will amount to some evidence only when it represents the overall substance of the expert's opinion and is based on more than purely speculative conclusions or personal opinion ungrounded in scientific reality." Id. at 542.

Even if the circumstances are such that the specific quantity of radiation exposure may not be ascertained, Plaintiffs can attempt to meet their burden with indirect evidence. The following factors, though not exhaustive, represent the type of indirect evidence which would be relevant to the issue of individual causation:

a. whether the neoplasm is radiogenic;

b. whether the diagnosis of the neoplasm occurred within a time frame consistent with scientifically established latency periods;

c. scientific literature indicating that the particular neoplasm is only susceptible to radiation induction at exposure levels far in excess of 10 rems;

d. whether Plaintiffs have ruled out other potential causes of the test Plaintiff's neoplasm

such as potential exposure to another toxic agent, genetic predisposition and smoking, among others;

e. scientifically reliable studies demonstrating a statistically significant increase in cancer incidence following the exposure to radiation;

f. indicia of radiation effects on plants and animals in the exposed area.

The court will neither apply these additional factors in a "checklist" fashion, nor base a ruling on causation on the presence or absence of any one of these factors.

It is important to note that by distinguishing conceptually between direct and indirect evidence, the court does not suggest that Plaintiffs must prove their case with only one type of evidence or the other. Rather, the court will use the above factors together with the 10 rem threshold to determine whether the quantum of Plaintiffs' evidence supports the inference of a causal link between the TMI accident and Plaintiffs' illnesses.

D. Application of the Law to the Facts of this Case

1. Were Plaintiffs Exposed to Radiation Released From TMI during the TMI Accident?

As the court interprets the Third Circuit's guidance, this element relates to any exposure, not to an exposure sufficient to induce a subsequent health effect. To determine whether

each Plaintiff was exposed to radiation, one must know what radionuclides were released from TMI during the accident, and the quantities of each radionuclide released, i.e. the source term. Plaintiffs' expert David Lochbaum does not, however, offer specific source term testimony. Rather, Plaintiffs offer Lochbaum to testify regarding a potential blowout, and to express his opinion regarding the quantity of radioactive noble gases released during the accident. As the court will discuss infra, because Lochbaum's opinions are too speculative to stand alone, and because Plaintiffs' other admissible evidence does not bolster his opinion, the court finds that Lochbaum's testimony regarding releases from the plant does not create a material factual dispute as to the TMI source term.

Nevertheless, the court finds that the record evidence submitted by Defendants supports the inference that Plaintiffs were exposed to radiation during the TMI accident. As part of their case, Defendants have presented a plethora of state and federal government reports. These reports are in agreement that, during the accident, populated areas within a 20 mile radius of TMI were likely exposed to minimal levels of ionizing radiation (under 100 mrems). Indeed, Defendants have conceded that readings at the plant boundaries exceeded the 0.5 rem regulatory threshold during the accident. In re TMI, 67 F.3d at 1119. The court liberally construes factor 2 of the TMI analysis to mean exposure to any amount of radiation released during the TMI accident. As a result, the court finds that there is no material factual dispute as to factor 2 of the TMI analysis. Plaintiffs were legally "exposed" to radiation. The court must, however, stress that its liberal interpretation of this factor would permit

a legal finding of "exposure" even at levels which are hundreds of times lower than natural background levels of radiation. As the court's discussion below will illustrate, a legal finding of "exposure," standing alone in the instant case, would be of little significance in establishing a genuine issue of fact as to the causation prong (factor 4) of the TMI analysis.

2. Was Radiation the Cause of Plaintiffs Injuries?

To create a material factual dispute as to this element of their case, Plaintiffs must produce evidence demonstrating that it is more likely than not that each of the test Plaintiffs' neoplasms were the result of their exposure to ionizing radiation during the TMI accident. Plaintiffs may carry this burden through the production of direct or indirect evidence of an exposure to a dose of radiation capable of inducing their neoplasms (i.e. in excess of 10 rems). To establish that each Plaintiff received a cancer inducing dose of radiation, Plaintiffs must first establish that quantities of radionuclides sufficient to deliver that dose were released from TMI during the accident. In essence, Plaintiffs need source term evidence demonstrating that releases were higher than those calculated by Defendants. See In re TMI, 911 F.Supp. at 829 n. 55 ("[d]espite its strong reservations, the court permitted [Lochbaum to make] this additional filing base upon the importance of this theory to Plaintiffs' case").[56]

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56. As the court indicated when discussing Plaintiffs' case, it is Plaintiffs' litigation strategy that has elevated the importance of this evidence. Because virtually all of Plaintiffs' experts (including those that have been excluded by the court's Daubert rulings), (Cont'd)

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As alluded to in the preceding discussion, Plaintiffs have no admissible source term evidence. Lochbaum's expert opinions, while methodologically sound, amount to little more than speculation regarding what might have happened in the plant during the accident. Because of the equivocal and arguably contradictory nature of Lochbaum's testimony, the court in its Daubert ruling questioned whether the testimony "fit" within the action. See In re TMI, 922 F.Supp. at 1052-53. That is, if Lochbaum's review of the relevant TMI data revealed no conclusive evidence of a blowout, how could his theories regarding how a blowout might have occurred assist a jury? In fact, during the Daubert hearings, Lochbaum went further than stating their was no "conclusive" evidence of a blowout — he testified that "I did not see any supporting indications that would lead me to believe that there was a blowout. . . . I do not believe that there was evidence of a blowout." (3/5/96 Tr. at 1455.) Plaintiffs are not required to conclusively prove that a blowout occurred. Rather, they must demonstrate that it is more likely than not that such an event occurred. Thus, insofar as other evidence, taken with the Lochbaum testimony, would make the probability of a blowout more likely than not, the court found that the proffered Lochbaum testimony would be helpful.

(Cont'd)
presumably at the direction of Plaintiffs' counsel, assumed high levels of exposure when stating their opinions, Plaintiffs needed at least one expert to provide the evidentiary foundation which supported these assumptions. Plaintiffs have ultimately failed to produce such an expert. As such, to the extent that Plaintiffs' expert opinions depend upon evidence of high releases from the plant, their opinions have been rendered invalid.

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Viewing all record evidence in a light most favorable to Plaintiffs, and making all reasonable inferences in favor of Plaintiffs, the court finds that there is insufficient dose evidence, discussed infra, to make Lochbaum's testimony helpful to the trier of fact.[57] While the law does not require Lochbaum to state his expert opinion with unwavering certainty, it does require him to state his expert opinion with a reasonable degree of professional certainty. The Third Circuit articulated this standard in Paoli II:

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57. A substantial portion of Plaintiffs' brief in opposition to Defendants' motion for summary judgment is devoted to a restatement of Lochbaum's report and hearing testimony. (See Pls.' Brief in Op. at 17-43.) Additionally, Plaintiffs call into question the scientific reliability of the Daniel Report, and argue that because Daniel's wife authored much of the report, Daniel should not be permitted to testify to the section that she authored. Plaintiffs filed no motions in limine to exclude any of Defendants' proffered expert testimony. Moreover, Plaintiffs' have misconstrued this court's November 9, 1995 order (and the rationale supporting the order discussed within the body of the court's 1/5/96 in limine ruling) regarding non-testifying experts. The court ruled that no expert could testify regarding the report of another where the testifying expert did not have the scientific expertise to intelligently discuss the methodology and scientific underpinnings of the report. In re TMI, 911 F.Supp. at 829. Accordingly, insofar as Daniel can speak intelligently to the work his wife performed on the report, and thereby afford Plaintiffs the opportunity to vigorously cross-examine, his testimony would be entirely proper. At the Daubert hearings, Daniel spoke intelligently on cross-examination, exhibited a firm understanding of the methodology employed in his report, and elicited no objection from Plaintiffs as to his qualifications to testify as an expert. The situation is analogous to the court's allowing Professor Shevchenko to testify to the substance of the cytogenetic analysis performed by Dr. Snigiryova.

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> When a party must prove causation through expert testimony the expert must testify with reasonable certainty that in his professional opinion, the result in question did come from the cause alleged . . . [I]f the plaintiff's . . . expert cannot form an opinion with sufficient certainty so as to make a [professional] judgment, there is nothing on the record with which a [factfinder] can make a decision with sufficient certainty so as to make a legal judgment.

Id. at 751 (quoting Cohen v. Albert Einstein Medical Ctr., 405 Pa.Super. 392, 592 A.2d 720 (1991), appeal denied, 529 Pa. 644, 602 A.2d 855 (1992)); cf. Ambrosini, 1995 WL 637650 at *3 (acknowledging that as "gatekeeper" a "judge is attempting to evaluate an expert's opinion to determine whether it is the 'hunch' of a knowledgeable scientist or if it is scientific knowledge based upon valid scientific principles and methodologies," and finding former insufficient to carry plaintiff's burden of proof at summary judgment). The court finds Lochbaum's opinions regarding the hypothesized hydrogen blowout to lack the certainty of a professional judgment. Id. Accordingly, despite being admissible and scientifically reliable for Daubert purposes, the evidence is insufficient to defeat a motion for summary judgment. See Daubert 509 U.S. at 595, 113 S.Ct. at 2798 (noting that granting summary judgment is an "appropriate safeguard[ ]" where evidence is admissible under Daubert but where the "scintilla of evidence presented . . . is insufficient to allow a reasonable juror to conclude that the position more likely than not is true"); see also Ambrosini, 1995 WL 637650 at *5 (finding that, although expert

testimony was not per se inadmissible under Daubert, testimony did not "fit" plaintiff's burden of proof in the absence of other evidence of causation"); see also Ruiz v. Whirlpool, Inc., 12 F.3d 510, 513 (5th Cir.1994) (noting that testimony based upon conjecture or speculation is insufficient to defeat summary judgment). Without a blowout, Plaintiffs are unable to demonstrate that release levels were significantly higher than originally presumed based upon the findings of the official studies of the TMI accident.

The balance of Plaintiffs' admissible evidence includes Dr. Wing's cancer incidence study, Professor Shevchenko's tree study and cytogenetic analysis, and Dr. Vergeiner's testimony regarding how prevailing weather conditions affected plume dispersion and travel. Taken together, this evidence does not bolster Lochbaum's testimony, create a material factual dispute, or carry Plaintiffs' burden of proof on the issue of causation.

Dr. Wing performed a reanalysis of the Hatch cancer incidence study. In conducting his reanalysis, Dr. Wing presumed that TMI area residents were exposed to levels (doses) of radiation significantly higher than those reported in the government reports discussed previously in this memorandum and the doses assumed by the Hatch study. See supra at 852-855 (discussing the reports and study). Based upon the assumption that residents were exposed to high levels of radiation, Dr. Wing appears to have attributed the increases in cancer association found in his study to exposure to high levels of radiation. The following colloquy from the Daubert hearings is illustrative:

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> Q. Turning to the cancer incidence study, your reanalysis of the Susser/Hatch data, if you assume that the real level of exposures, not the relative units, but the real level of exposures was small or was low as postulated in the Susser/Hatch report, that would affect your interpretation of the data; correct?
>
> A. Let me put it this way: If I assumed that it was not possible that the doses were higher, than assumed by the authors of the Columbia [Susser/Hatch] paper, then it would prohibit making a causal interpretation of the observed association.

(11/21/95 Tr. at 981-82 (testimony of Dr. Wing).) In this same vein, Dr. Wing states in his report "[u]nlike the original reports based on these data, our re-analyses (sic) assumed that absolute accident doses could have been large enough to produce measurable impacts on cancer incidence. . . ." (2/25/95 Wing Report at 9.) The record presently before the court does not support the fundamental assumption made by Dr. Wing — that doses were significantly higher than originally estimated. In the absence of this assumption, Dr. Wing himself admits that he would be unable to make a causal interpretation based upon his findings. Because Plaintiffs have presented no evidence in support of this assumption, the court finds the Wing cancer incidence study does nothing to assist Plaintiffs in creating a material factual dispute or meeting their burden of proof. Cf. Kearney v. Philip Morris, Inc., 916 F.Supp. 61 (D.Ma.1996) (finding that premise upon which experts founded their opinions "involves an inferential leap for which no reasoned basis is

proffered, and thus does not survive reasoned scrutiny" at summary judgment).

Because the Wing study offers no support to Plaintiffs' case, Plaintiffs are left with the Shevchenko cytogenetic analysis and tree study as their sole evidence that high doses of radiation reached populated areas and caused Plaintiffs' neoplasms. The cytogenetic analysis demonstrates that some of the 29 blood samples, taken more than fifteen years after the accident, show elevated levels of dicentric chromosomes. However, the number of dicentric chromosomes will decrease substantially in the first year following exposure; and thus, cytogenetic analysis become less accurate over time. Plaintiffs have presented no scientific evidence that would support a finding that the Shevchenko cytogenetic analysis, performed more than fifteen years after the TMI accident, is more than a minimally accurate means of proving prior exposure to radiation.[58] Were there other, stronger

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58. There is scientific evidence on the record which indicates that a cytogenetic analysis performed using the FISH method would accurately measure chromosome aberrations long after the initial exposure to radiation. However, at the commencement of the Daubert hearings, more than one year after the formal close of discovery, Plaintiffs' experts had failed to complete a FISH method analysis of the 29 TMI blood samples. The court notes that on the day that the Daubert hearings began, more than seventeen years had elapsed since the date of the TMI accident, and more than seven years had elapsed since the many separate personal injury actions had been consolidated under the instant case number. Plaintiffs had ample time to complete a FISH method analysis prior to the hearings, yet they failed to do so. Cf. Cooley v. Pennsylvania Housing Finance Agency, 830 F.2d 469, 474 (3d Cir.1987) ("If complete and adequate discovery has been afforded to the parties, then the case of the party bearing the ultimate burden of proof can be put to task by the opposition through a Rule 56 motion.").

evidence of exposure to greater than 10 rems of radiation on the record, the cytogenetic analysis would bolster that evidence. Absent such evidence, the cytogenetic analysis results alone do not create a material factual dispute on the issue of dose.

Finally, Plaintiffs offer the Shevchenko tree study in support of their assertion that high levels of radiation reached populated areas during the accident. Professor Shevchenko likely has more personal experience making first hand observations of radiation exposed areas than any other expert involved in this litigation. His credentials are impressive. Plaintiffs offer Professor Shevchenko to testify that the trees he observed in the TMI area similar in appearance to the radiation exposed trees that he has observed in the former Soviet Union at sights such as Semipalatinsk, Chernobyl and Kyshtym. His testimony is extremely powerful insofar as it appears to place the TMI accident in the same realm with the Chernobyl accident.

Plaintiffs argue that based upon the many studies he has conducted in the former Soviet Union over his career, Professor Shevchenko can visually identify trees that have been damaged by radiation exposure. Moreover, Plaintiffs claim that he can distinguish by observation alone damage to trees caused by pathogens, insects or lightening and damage caused by radiation. The record reveals that Professor Shevchenko's experience in identifying radiation damage in trees in the former Soviet Union derives from his studies of the cellular and subcellular effects of the exposure. Indeed, his observations of tree damage in the former Soviet Union were made in conjunction with subcellular analyses of tree tissue. (See 11/22/95 Tr. at 1195.) However, Professor

Shevchenko has not performed similar studies on the trees he observed in the TMI area. (Id. ("No. I have not conducted such investigation (sic). It would demand a lot of time. . . . I did not have such an opportunity.").) When asked whether he had an opinion as to what caused the flat top on a TMI pine tree, Professor Shevchenko indicated "Yes. I believe this is the effect of radiation, because we have observed these things in Semipalatinsk, Kyshtym and Chernobyl." (11/21/95 Tr. at 1088.) In qualifying his answer, Professor Shevchenko explained that one of the reasons he chose to include pine trees in his study was because "[i]n our lab as well as in other labs, investigation has been conducted on radiation genetics on pine trees." (Id. at 1089.)

Both the damage in tree tops observed by Professor Shevchenko and the chromosome dicentrics are nonspecific effects of radiation exposure. They are classified as nonspecific because the same effects can be caused by things other than radiation. Professor Shevchenko will testify that based solely upon his observation of TMI trees, it is his professional opinion that the trees were damaged as a result of radiation exposure during the TMI accident. Effectively, Professor Shevchenko is asserting that his expertise is so great that he simply knows radiation damage when he sees it. To the extent that Professor Shevchenko's confidence in his abilities is warranted, the record nevertheless reflects that his observations were cursory. Professor Shevchenko testified that he did not examine the tops of trees from a bucket truck, or by having sections cut out and brought down to him for investigation, and that he does not have sufficient expertise to evaluate non-radiation induced diseases in trees. (11/22/95 Tr. at 1184-85.) Without disputing his acumen in this area, the court finds that Professor Shevchenko's

testimony that selected trees in the TMI area look like trees exposed to radiation at Semipalatinsk, Kyshtym and Chernobyl is simply insufficient to carry the weight of Plaintiffs' entire case. Combining the cytogenetic evidence and the tree evidence likewise fails to carry Plaintiffs' burden. Two nonspecific effects of radiation exposure cannot meld to equal proof of specific exposure to radiation.

Finally, Dr. Vergeiner's testimony was admitted by the court subject to the condition that Plaintiffs could explain how the testimony was still relevant in light of the court's exclusion of the bulk of Dr. Vergeiner's proffered expert testimony. Had Plaintiffs presented admissible evidence demonstrating that significant quantities of noble gases were released from TMI during the accident, Dr. Vergeiner's testimony would assist the jury in understanding how prevailing weather conditions effected the plume's path and the rate at which it dispersed.[59] However, on the current state of the record, Plaintiffs have no high release evidence. Without high releases, there is no dense yet narrow plume, and there is no need for Dr. Vergeiner to explain how such a plume might have evaded the TLDs set up to monitor airborne radiation.

Viewing all evidence before the court in a light most favorable to Plaintiffs, the court finds the evidence

59. At the time the Vergeiner testimony was conditionally admitted, Plaintiffs had no record source term evidence. Dr. Webb had been withdrawn, and the court had yet to receive the Lochbaum report. Based upon counsels' characterization of the expected findings of the Lochbaum report (e.g. that a blowout occurred), the court found that Dr. Vergeiner's meteorological testimony might prove helpful to a jury.

insufficient to create any material factual dispute and insufficient to carry Plaintiffs burden of proof at trial. Plaintiffs have neither presented direct evidence that they were exposed to doses of radiation greater than 10 rems, nor have they presented indirect evidence capable of supporting the inference that they were exposed to cancer inducing levels of radiation. Accordingly, the court will grant Defendants' motion for summary judgment in its entirety.

IV. Conclusion

The parties to the instant action have had nearly two decades to muster evidence in support of their respective cases. As is clear from the preceding discussion, the discrepancies between Defendants' proffer of evidence and that put forth by Plaintiffs in both volume and complexity are vast. The paucity of proof alleged in support of Plaintiffs' case is manifest. The court has searched the record for any and all evidence which construed in a light most favorable to Plaintiffs creates a genuine issue of material fact warranting submission of their claims to a jury. This effort has been in vain. The grave consequence of the court's decision to grant summary judgment in favor of Defendants is obvious — thousands of individuals who believe that they have suffered adverse medical effects as a result of the TMI accident will not have an opportunity to have their claims heard by a jury of their peers. In addressing the merits of Defendants' motion for summary judgment, however, this case is like all others that come before the court in that the well articulated standards governing the award of summary judgment guide the court's evaluation of the evidence before it. Those standards combined with the scarcity of evidence of record to support Plaintiffs' claims mandate the result reached by the court today.

APPENDIX E — MEMORANDUM AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF PENNSYLVANIA DATED APRIL 2, 1996

In re TMI LITIGATION CASES
CONSOLIDATED II.
This Document Relates to: All Plaintiffs.

Civil Action No. 1:CV-88-1452.

United States District Court,
M.D. Pennsylvania.

April 2, 1996.

* * *

MEMORANDUM

RAMBO, Chief Judge.

Presently before the court are a number of unresolved evidentiary and discovery matters. On February 12-16 and March 1, 4-5, 1996, the court conducted a "second round"[1] of in limine hearings related to Defendants' motions to exclude certain of Plaintiffs' expert witnesses. Initially, it was contemplated that this second round would be devoted solely to Plaintiffs' medical causation experts. Due, however, to time constraints and scheduling difficulties during the first round of hearings, issues relating to some of Plaintiffs' dose

1. The "first round" of hearings was conducted in November 1995, and focused upon Plaintiffs' dose experts.

experts were carried over into the second round. All in limine hearings are now complete, as is all briefing on outstanding discovery and evidentiary matters. Accordingly, the instant memorandum will reach the merits of the following issues: (1) whether Plaintiffs' supplemental expert reports, filed subsequent to the deadlines for filing expert reports, are admissible pursuant to Rules 26 and 37 of the Federal Rules of Civil Procedure; (2) whether the court should reconsider its January 5, 1996 ruling with respect to the proffered testimony of Vladimir Shevchenko; (3) whether, in light of further briefing on the rate of error issue, the court finds the Wing cancer incidence study to be scientifically reliable and therefore admissible; and (4) whether Plaintiffs' experts Olga Tarasenko, David Lochbaum, Bruce Molholt, Theodor D. Sterling, Luis Fajardo, Thomas H. Winters, and Sigmund Felix Zakrzewski should be permitted to testify pursuant to the Federal Rules of Evidence, Daubert v. Merrell Dow Pharmaceuticals, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993) and In re Paoli Railroad Yard PCB Litigation, 35 F.3d 717 (3d Cir.1994).[2]

I. Plaintiffs' Filing of Expert Reports

Defendants have objected, both in their filings and during the in limine hearings, to the admission of supplemental expert reports filed by Plaintiffs subsequent to the court ordered filing deadlines. For the most part, the court has avoided piecemeal rulings on this issue opting instead to

2. As the facts are well known to the parties, the court will not reiterate them again here. The factual background of this case is set forth more fully in this court's memorandum of law dated January 5, 1996.

make one uniform ruling. But see In re TMI, Mem.Op. (M.D.Pa. November 9, 1995) (granting Defendants' motion in limine as to certain untimely filed expert reports). The issue is now ripe for disposition. A brief background discussion will place matters in context.

A. Case Management History

The timeliness issue has recurred in many settings within this litigation and has been particularly troubling to the court. Historically, the court has encountered significant difficulty in keeping the parties adhered to any case management order. As a result, there have been close to a dozen "case management orders." 7/10/92 Proposed Schedules of Plaintiffs and Defendants for Taking Cases to Trial; 6/15/93 Case Management Order (setting jury selection for 7/6/94); 11/12/93 Revised Case Management Order (moving jury selection to 10/3/94 at the request of parties); 5/13/94 Order Amending Case Management Schedule (moving jury selection to 4/13/95); 7/28/94 Order (granting Plaintiffs' request for further amendment of pre-trial schedule); 10/14/94 Order (further amending pre-trial schedule at Plaintiffs' request, and noting that absent extreme and compelling circumstances no further amendments will be entertained); 10/19/94 Order (directing parties to submit final joint case management schedule in response to correspondence from counsel); 11/3/94 Order (adopting parties' final joint case management schedule, noting that said order is binding and that it will not be amended absent extreme and compelling circumstances); 5/8/95 Order (moving jury selection to 6/3/96). Much to its own detriment, the court has been flexible and accommodating with respect to the pre-trial schedule.

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In November 1994, having grown weary of the parties' inability to comply with set deadlines and fearing that the instant action would languish, the court ordered the parties to draft a final joint case management schedule. On November 3 the court adopted the schedule proposed by the parties and again indicated that the schedule would not be altered absent extreme and compelling circumstances. On May 8, 1995, the court issued an order supplementing the November 1994 case management order to place the case on the June 1996 trial list. Since the entry of the May 8 order, the court, although permitting minor alterations to the schedule, has denied any motion to amend that would effectively remove the case from the June 1996 trial list.

The captioned action, involving approximately 2,000 Plaintiffs, was consolidated under one case number in 1988. To an extent, circumstances beyond the court's control, such as the filing of interlocutory appeals and Congress's amendment of the Price Anderson Act, have stymied the prompt resolution of this action. Nevertheless, a review of the docket reveals that the test cases's torpid progression toward trial is due in part to the parties' willingness to stipulate to extensions of time and alterations of the case management schedule and the court's historical willingness to accommodate such requests.[3]

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3. It should be noted that often the alterations to the case management schedule were for the purpose of conducting additional discovery. See, e.g. 5/13/94 Order; 7/28/94 Order; 11/3/94 Order.

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B. Plaintiffs' Expert Reports

Defendants object to the admission of all of Plaintiffs' expert reports and supplemental affidavits filed subsequent to the court ordered filing deadlines. Although tedious, the following review of Plaintiffs practice in filing expert reports is warranted.

Pursuant to an order dated May 13, 1994, Plaintiffs were to file the expert reports of James Gunckel, Richard Webb and Ignaz Vergeiner not later than August 1, 1994. This order also directed that expert reports on medical causation were to be filed not later than September 1, 1994 and that expert reports on punitive damages were to be filed not later than October 1, 1994. On August 1, 1994, Plaintiffs filed the 6/94 report of Ignaz Vergeiner ("TMI Treatise 1"), and the 5/26/94 and 8/1/94 affidavits of Douglas Crawford-Brown. On August 4, 1994, Plaintiffs filed the 8/1/94 preliminary report of Richard Webb entitled "A Preview Short Synopsis." Thus, the report of James Gunckel was not timely filed on August 1, and the August 4 filing of the Webb "Preview" was both untimely and in contravention of Rule 26(a)(2) of the Federal Rules of Civil Procedure ("The report shall contain a complete statement of all opinions to be expressed and the basis and reasons therefor . . ."). The court was remiss in not striking these filings immediately and, in temporarily overlooking these rule violations, the court may have unwittingly encouraged Plaintiffs' improper conduct. The record reflects that these 1994 filings were only the first in a long stream of improper and untimely filings.

On September 15, 1994, one and one-half months after the filing deadline, Plaintiffs filed the 7/6/94 Affidavit of

Vladimir Shevchenko. On November 3, 1994, the court entered the final joint case management schedule. This schedule extended the deadline for Plaintiffs' filing of dose and medical causation expert reports to March 1, 1995.[4] On March 1, Plaintiffs filed the expert "reports"[5] of the following experts: Armentrout, Crawford-Brown, Gunckel, Hinrichesen, Lochbaum, Shevchenko, Vergeiner, Webb, Wing, Fajardo, Winters, Zakrzewski. On March 14, without leave of court, Plaintiffs supplemented their March 1 filing with the reports of Shevchenko, Tascaev, Kozubov, Popov, Portman, Tarasenko, and Snigiryova. On March 15, again without leave of court, Plaintiffs supplemented their March 1 filing with the report of Bruce Molholt. Finally, on March 29, without leave of court, Plaintiffs filed a third supplement to the March 1 filing adding to the reports of Shevchenko and Zakrzewski. Thus, as of April 1995, Plaintiffs had late-filed a significant portion of their expert reports on dose and medical causation.

In February 1995, the court issued a preliminary memorandum of law related to Defendants' motion in limine to exclude Dr. Molholt's 4/8/93 report, and ordered limited additional briefing with respect to certain of the Paoli II

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4. The court notes that insofar as this order has retroactive application it cures the timeliness defects in Plaintiffs prior filings.

5. In large part, these filings are not "reports" in the traditional sense of the word. For many of Plaintiffs' experts, a "report" consists of a compilation of affidavits updated over time. See, e.g., Report of Douglas Crawford-Brown (2/27/95 Aff.; 8/1/94 Aff.; 6/10/94 Aff.; 5/26/94 Aff.); Report of Steven Wing (2/25/95 Aff.; 2/23/95 Aff.; 1/12/95 Aff.; 10/31/94 Aff.; 6/13/94 Aff.; 1/94 Aff.; 3/16/93 Aff.).

factors.[6] In re TMI, Mem.Op. at 22 (M.D.Pa. February 14, 1995) ("[T]he court has invited the parties to respond concisely to the issues raised . . . this is not an invitation to deluge the court with paper. Clear, concise, relevant information will assist the court in reaching a just resolution; likewise, the submission of frivolous or irrelevant information will be frowned upon.") As exhibits to their court-ordered filing, Plaintiffs submitted several new expert reports (5/1/95 Molholt; 4/24/95 Kerman; 5/2/95 Kerman; 2/27/95 Crawford-Brown). In September 1995, Plaintiffs, again without leave of court, untimely filed the reports of Theodore Sterling and Ronald Kerman.

The next battery of Plaintiffs' expert reports were filed as exhibits to their opposition to Defendants' motion in limine to exclude Plaintiffs' dose experts. On October 25, Plaintiffs filed as exhibits the updated reports of the following experts: Vergeiner (two separate affidavits dated 10/18/95), Armentrout (10/10/95 Aff.; 10/22/95 Aff.), Gunckel (8/23/95 Aff.), Shevchenko (10/6/95 Aff.), Wing (10/19/95 Aff.), Crawford-Brown (10/20/95 Aff.), Molholt (9/8/95 Aff.; 9/14/95 Aff.). On October 31, with leave of the court,[7]

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6. The court directed the additional briefing to clarify the parties' positions and to assist the court in reaching a final determination on the admissibility of the proffered testimony of Dr. Molholt.

7. Through a Memorandum and Order dated October 19, 1995, the court re-opened discovery from October 20 to October 30 for the purpose of granting Plaintiffs access to original plant data stored at the Emaus Street repository. The court granted Plaintiffs motion

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Plaintiffs' supplemented the record with the following affidavits/new reports: Armentrout (9/20/95 Aff.; 5/11/95 Aff.), Blanch (10/31/95 Aff.), Kerman (10/30/95 Aff.), King (10/30/95 Aff.), Reyblatt (10/31/95 Aff.), Shevchenko (10/6/95 Aff.), Kozubov (9/12/95 Aff.), Smirennyi (10/30/95 Aff.), Wing (10/27/95 Aff.). On January 16, 1996, as exhibits to a brief in opposition to Defendants' motion to compel, Plaintiffs filed the following supplemental affidavits: Crawford-Brown, Ornstein, Purcell, Reyblatt. Finally, during February 1996, Plaintiffs filed the following supplemental affidavits without leave of court: Wing (10/19/95 Aff.; 1/26/96 Aff.; 1/31/96 Aff.; 2/7/96 Aff.), Kozubov (1/30/96 Aff.), Armentrout (2/1/96 Aff.), Milhollin (5/5/96 Aff.), Griffin (1/30/96 Aff.), King (2/16/96 Aff.).

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to compel despite the fact that "[a]fter sitting on their right to access these materials for nearly one decade, Plaintiffs now, one week before their brief on the in limine issues is due and after the formal close of discovery, request that Defendants be compelled to produce the aforementioned documents merely because it would not be inordinately difficult for Defendants to do so." 10/19/95 Order at 3. Plaintiffs offered the court no explanation as to why they had failed to view this material during the formal discovery period. Id.

Pursuant to its granting the motion to compel, the court allowed Plaintiffs "to supplement their brief in opposition to Defendants' motion in limine." The court allowed Plaintiffs to supplement the record to the extent that something in the original strip chart data proved helpful to their case. Plaintiffs were not granted permission to supplement the record with anything beyond the scope of the "new" original plant data.

C. Discussion

Rule 26(a)(2) of the Federal Rules of Civil Procedure governs the disclosure of expert testimony. In relevant part Rule 26 provides as follows:

> (B) Except as otherwise stipulated or directed by the court, this disclosure shall, with respect to a witness who is retained or specially employed to provide expert testimony in the case or whose duties as an employee of the party regularly involve giving expert testimony, be accompanied by a written report prepared and signed by the witness. The report shall contain a complete statement of all opinions to be expressed and the basis and reasons therefor; the data or other information considered by the witness in forming the opinions; any exhibits to be used as a summary of or support for the opinions; the qualifications of the witness, including a list of all publications authored by the witness within the preceding ten years; the compensation to be paid for the study and testimony; and a listing of any other cases in which the witness has testified as an expert at trial or by deposition within the preceding four years.

Fed.R.Civ.P. 26(a)(2)(B). Rule 37 provides for self-executing discovery sanctions where a party fails to disclose information subject to the mandatory disclosure provisions of Rule 26(a). Specifically, Rule 37 states:

> (1) A party that without substantial justification fails to disclose information required by Rule

> 26(a) . . . shall not, unless such failure is harmless, be permitted to use as evidence at a trial, at a hearing, or on a motion any witness or information not so disclosed.

Fed.R.Civ.P. 37(c)(1). While the Rule itself does not specifically delineate the types of non-disclosure that are harmless, the advisory notes to the 1993 amendment of Rule 37 do provide some guidance as to the type of non-disclosure envisioned as harmless:

> Limiting the automatic sanction to violations "without substantial justification," coupled with the exception for violations that are "harmless," is needed to avoid unduly harsh penalties in a variety of situations: e.g., the inadvertent omission from a Rule 26(a)(1)(A) disclosure of the names of a potential witness known to all parties; the failure to list as a trial witness a person so listed by another party; or the lack of knowledge of a pro se litigant of the requirement to make disclosures. In the latter situation, however, exclusion would be proper if the requirement for disclosure had been called to the litigant's attention by either the court or another party.

Advisory Notes to 1993 Amend.Fed.R.Civ.P. 37(c). Although the captioned action was filed prior to the most recent amendment of Rules 26 and 37, the bulk of expert discovery has been conducted subsequent to the 1993 amendments. Accordingly, the court finds that Rules 26 and 37, as amended in 1993, are binding upon the parties.

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The Court of Appeals for the Third Circuit, interpreting Rule 37 narrowly, "has been reluctant to approve the exclusion of testimony unless a party has (1) revealed previously undisclosed evidence when trial was either imminent or in progress, or (2) acted in bad faith." Diflorio v. Nabisco Biscuit Co., 1995 WL 710592 at *2 (E.D.Pa. Nov. 13, 1995). Moreover, the Third Circuit has held that lack of diligence does not constitute bad faith. Paoli II, 35 F.3d at 793. Through Paoli II, the Third Circuit signaled the continuing applicability of Meyers v. Pennypack Woods Home Ownership Ass'n, 559 F.2d 894 (3d Cir.1977), to a district court's Rule 37 analysis. Pursuant to Pennypack, a court must consider:

> (1) the prejudice or surprise in fact of the party against whom the excluded witnesses would have testified, (2) the ability of that party to cure the prejudice, (3) the extent to which waiver of the rule against calling unlisted witnesses would disrupt the orderly and efficient trial of the case or of other cases in the court, and (4) bad faith or willfulness in failing to comply with the district court's order[,]

Paoli II, 35 F.3d at 791 (citing Pennypack, 559 F.2d 894), when determining whether to impose Rule 37 sanctions. The discussion below will support the court's finding that (1) Defendants would be prejudiced by the admission of certain of the untimely reports[8] insofar as the rigorous

8. To develop the record during the in limine hearings, the court permitted testimony with respect to some untimely filed reports. (Cont'd)

pre-trial schedule precludes them from having sufficient time to prepare to cross-examine on the late-filed reports; (2) Defendants are unable to cure the prejudice insofar as the court is unwilling to further alter the pre-trial schedule because such alteration would necessitate postponing the trial date; (3) waiver of the Rule 37 sanctions would disrupt the orderly trial of this case as well as a multitude of other cases on the court's docket; and (4) Plaintiffs repeated violation of numerous orders of this court, failure to seek leave of court before filing untimely reports, and "covert" filing of additional reports as exhibits to a variety of unrelated motions rather than "overtly" making supplemental filings, rises to the level of bad faith.

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This testimony was uniformly subject to Defendants' continuing objections based upon untimeliness and failure to include the methodology or information in the expert's original report. The court's ruling as to what testimony would be permitted subject to the continuing objection was based upon its consideration of the following factors: (1) when Defendants acquired knowledge of the new information in proximity to the commencement of the relevant in limine hearing; (2) whether Defendants' had an adequate opportunity to depose the witness as to the new and untimely materials; (3) whether, in light of the complex nature of the testimony, allowing Defendants wide latitude to cross examine at the hearings would cure any potential prejudice; (4) whether Defendants had sufficient knowledge of the methodology/ information at the time of the hearing to conduct an adequate cross-examination of the witness. The court will make its ultimate ruling on Defendants' continuing objections in the context of its discussion of Defendants' motion in limine to exclude Plaintiffs' medical causation experts.

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In Paoli II, the Third Circuit reversed the district court's exclusion of testimony contained within an untimely filed expert report. Paoli II, 35 F.3d at 792. The Third Circuit provided the following explanation for finding error with the district court's ruling:

> We have great difficulty with the district court's rulings. The prejudice to the defendants here is extremely minimal. Plaintiffs properly identified Dr. DiGregorio as a witness by the March 17 deadline, thus the defendants knew that he was going to testify. They were also aware of the general substance of his testimony and even some of the specifics of his plan for medical monitoring. . . . Moreover, defendants were provided with all of the specifics of Dr. DiGregorio's proposed medical monitoring plan on April 18, only a month after the district court's deadline, four months before the schedule trial date, and 60 days before the deadline the district court has set for ending discovery. Thus, the defendants has abundant time to depose Dr. Digregorio regarding the specifics of his proposed program before the discovery deadline, and the district court could easily have extended the deadline to provide the defendants more time.
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> [W]e have reversed an exclusion where, as is the case here, there was only a slight deviation from pre-trial notice requirements, and admitting the

> witness was likely to cause only slight prejudice to the defendants, who were already aware of the basic substance of the witness' testimony.

Id. The situation facing this court can be distinguished from the above-referenced Paoli II scenario on a number of levels. First, all of the untimely supplemental reports at issue here were filed after the formal close of discovery. Where, as here, discovery was formally open for nearly one decade, and where the court readily accommodated requests for enlargement of the deadlines on a number of occasions, Plaintiffs' failure to timely file expert reports without any justification is inexcusable. Second, although it appears that the witnesses whose reports are at issue were identified in a timely fashion, the substance of their testimony was largely unknown to Defendants. The timely filed "preliminary"[9]

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9. This court's research has revealed only one written opinion confronting the issue of whether a "preliminary" report meets the disclosure requirements of Rule 26. In Smith v. State Farm Fire and Casualty Co., 164 F.R.D. 49, 53-54 (S.D.W.Va.1995), the district court made the following observations:

> A "preliminary" report is not contemplated by the Rule, which calls for "a complete statement of all opinions to be expressed." . . . These reports fulfill none of the purposes of the Rule as they leave Defendants open to unfair surprise. If Defendants depose each expert to avoid the risk of ambush, no resources are conserved. The reports refer to massive amounts of documents as the basis for the opinions which are expressed in vague terms, with few specific references.

Id. This court is in agreement with the Smith court. As such, it finds Plaintiffs' arguments that Defendants have not been prejudiced by

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reports of many of Plaintiffs experts bear little resemblance to the supplemental reports that Plaintiffs would have this court admit. Compare 4/8/93 Molholt with 3/13/95 Molholt and 5/1/95 Molholt.[10] Moreover, these supplemental filings continued to be made up to, during, and after both rounds of in limine hearings.

Were the instant action a less complex lawsuit, the court would be more inclined to find Plaintiffs' Rule 26 violations harmless. See In re Ford Motor Co. Bronco II Products Liability Litigation, 1996 WL 28517 (E.D.La. January 23, 1996) (noting that "[c]ompliance with the disclosure

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Plaintiffs' Rule violations, to exhibit a profound misunderstanding of the policy considerations underlying the disclosure requirements of Rule 26. As the purpose of mandatory disclosure is to streamline the discovery process and avoid unnecessary depositions, the fact that Plaintiffs' reports were "preliminary" and thus incomplete, thereby necessitating lengthy depositions, supports the proposition that Plaintiffs flagrantly violated Rule 26 and that Defendants were prejudiced by Plaintiffs violation of the Rule.

10. The court finds this to be particularly relevant in light of the Third Circuit's observation in Paoli II that the plaintiffs there "had little to gain from the month delay in provision of the additional material." Paoli II, 35 F.3d at 793. Here, Plaintiffs had much to gain from delaying the final disclosure of the expert opinions. By examining each expert's series of affidavits chronologically, it is readily apparent that methodologies grew more "scientific", new graphs and charts were added, new information was integrated into the methodology, etc., in direct response to legal challenges raised in a variety of Defense motions. Thus, by making their untimely supplemental filings, Plaintiffs were able to mold their expert reports to meet Defendants' legal challenges.

requirements is particularly important in complex cases"); United States v. Davis, 1993 WL 525591 at *1 (D.R.I. April 16, 1993) ("At trial in this case, expert witnesses are expected to testify about complex scientific and technical issues. . . . To adequately prepare for trial, each side must have detailed, final information regarding opposing expert witnesses' testimony and the theories and documents upon which the expert will rely.") Under the unique circumstances of this case, however, Plaintiffs' Rule violations have prejudiced Defendants' ability to adequately prepare their case for trial, and have effected this court's ability to manage the case. In re Ford Motor Co., 1996 WL 28517 at *2 ("Plaintiffs noncompliance has caused inconvenience to both the defendant and the court. As a result, it is difficult to find plaintiffs' conduct "harmless" within the meaning of Rule 37(c)(1) and to unconditionally exempt plaintiffs from the harsh sanction which Rule 37 advocates."). The administrative ramifications of this court's decision to set a June 1996 trial date are enormous. Accommodating the parties for two rounds of in limine hearings required clearing the court's calendar for most of November 1995, part of February 1996, and part of March 1996. Further, the court has cleared its calendar for the months of June, July and part August 1996 for trial in this matter. The court's docket, aside from the instant action, is substantial. Making the resolution of this case a priority has caused numerous other litigants, who are equally deserving of their "day in court," to be inconvenienced.

The court is resolute in its belief that had it done nothing to prod this case to trial, motions for further extension of the discovery deadlines would still be being filed. Nevertheless,

because the court has taken such drastic measures to ensure that this matter does finally go to trial, the court must be somewhat rigid in its adherence to the pre-trial schedule. Knowing in advance that this would be the case, the court permitted the parties to participate in drafting the final pre-trial schedule. The court adopted the parties' proposed schedule in its entirety and set a firm trial date. Further, the court repeatedly admonished the parties that once the schedule was put in place it would not be altered absent extreme and compelling circumstances. See, e.g. 10/14/94 Order; 11/3/94 Order. Finally, the court has not been entirely inflexible with all deadlines, allowing alteration of the final pre-trial schedule where such alteration would not effect the set trial dates.

Related and equally important to the question of whether the untimely filings should be admitted is Plaintiffs' consistent inability to articulate any substantial justification for their inability to timely file complete expert reports. Plaintiffs' counsel simply argue that there has been no prejudice to Defendants because trial is still several months away, and that they are doing everything within their power to comply with the court's rigorous pre-trial schedule. (Pls.' Findings at 69 ("Even assuming that this information was submitted untimely, the Court can find no prejudice to the defendants").) These responses are unavailing as the court finds that Plaintiffs have offered no substantial justification for their untimely filings, and admission of certain of Plaintiffs' supplemental filings would prejudice Defendants. R.C.M. Exec. Gallery Corp. v. Rols Capital Co., 1996 WL 30457 at *2 ("defendants are prejudiced if they are unable to rely on court-imposed deadlines, and judicial

efficiency is impaired if such deadlines are ignored with impunity"); Heflin v. City of Chicago, 1996 WL 28238 at *8 (N.D.Ill. Jan. 22, 1996) ("Defendants argument that their is still time to [conduct discovery] . . . before trial is unavailing. The court will not circumvent Rule 37's inducement for full compliance with Rule 26(a)(2) and disrupt . . . trial preparation without substantial justification.").

In Sierra Club, Lone Star Chapter v. Cedar Point Oil Co., Inc., 73 F.3d 546 (5th Cir.1996), the United States Court of Appeals for the Fifth Circuit recently upheld a district court's exclusion of incomplete and untimely filed expert reports under circumstances similar to those here. Finding that the district court did not abuse its discretion in excluding the expert testimony, the Fifth Circuit Court made the following observations:

> [Plaintiff] even appears at times to admit that it did not comply with the discovery order by stating that it was "impossible" to comply and that their experts "did all they could do" under the circumstances. The reasons for noncompliance, however, are relevant to the separate issue of whether the sanction imposed was appropriate. On the other hand, a violation of an order is a violation of an order, regardless of the reasons therefor.

Id. at 571 n. 46. In commenting upon the propriety of excluding the testimony as a sanction for the discovery violations, the appellate court noted that "[w]hile a

continuance would have given [the defendant] . . . more time to review the late disclosures, such a measure 'would neither punish [plaintiff] . . . for its conduct nor deter similar behavior in the future.' " Id. at 573 (quoting Bradley v. United States, 866 F.2d 120, 126 (5th Cir.1989)).

The United States District Court for the Eastern District of Pennsylvania has also recently confronted the issue of untimely supplemental expert reports filed in complex tort litigation. Denying the plaintiffs' motion to submit supplemental expert reports after the close of discovery, the district court found that "the process of producing new expert reports, deposing the new experts, producing responsive reports from defense experts, and subjecting the new experts to in limine scrutiny would unduly delay the final disposition of these cases." In re Paoli Railroad Yard PCB Litigation, 1996 WL 24751 at *2 (E.D.Pa. January 24, 1996). The court noted that the plaintiffs had failed to demonstrate that it was impossible for them to have been more diligent in conducting discovery while discovery was open and that the "[p]laintiffs had from 1987 to 1992 to find a medical expert who could render an opinion in their cases." Id.

The court finds the facts of the instant case to be as compelling as both Sierra Club and Paoli. Plaintiffs have consistently flouted filing deadlines with impugnity, and have failed to meet the most basic Rule 26 disclosure requirements.[11] Moreover, Plaintiffs have had from 1979 to

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11. Plaintiffs have had difficulty meeting virtually every filing deadline in the past year. It is commonplace for the court to receive a telephone call from Plaintiffs' counsel at approximately 4:45 p.m.

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1995 to find expert witnesses to support their case. As such, the court finds suggestion that Plaintiffs experts have been pressed for time to ring hollow. Additionally, as the court discussed at length above, the court finds that admission of the untimely filed supplemental reports would prejudice Defendants and further disrupt the efficient functioning of this court.[12] Based upon the foregoing, the court finds adequate grounds, pursuant to Federal Rules of Civil Procedure 26 and 37, to exclude from the record certain supplemental expert reports filed without leave of court

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on the day of a filing deadline indicating that Plaintiffs' will be unable to get their filing to the Clerk's office before the close of business. On numerous occasions, the court has permitted Plaintiffs' to deliver their filings directly to chambers after hours and on weekends. The court made this gesture to avoid what it believed to be the unduly harsh alternative of refusing to accept the filing. The court presumes that, on occasion, even the most diligent attorney will encounter circumstances beyond her control which make it unable for her to meet a filing deadline. Plaintiffs' counsel have, with their consistent inability to meet deadlines, challenged this court's presumption that their failure to make timely filings was truly due to circumstances beyond their control.

12. While there are technically still three months until jury selection, the relative proximity to trial becomes apparent when viewed through the case management schedule. Two of the remaining three pre-trial months will be used by the parties for briefing on summary judgment motions. In the remaining month before trial, while the court rules on summary judgment motions, the parties will likely be deeply enmeshed in final trial preparation work. It would be unreasonable, in light of this compressed schedule, to expect Defendants to digest and incorporate into their case the array of supplemental filings that Plaintiffs' seek to have admitted.

subsequent to the court ordered filing deadlines. (See also Pls.' Answer to Defs' Motn. to Preclude any Additional Reports or Related Testimony from Richard Webb at 4 ("it is the flouting of a court's scheduling order that typically produces a severe sanction").) Looking solely at the conduct of Plaintiffs' counsel, the court finds it appropriate to exclude all expert reports filed subsequent to court-ordered filing deadlines. This, however, would result in an effective dismissal of much of Plaintiffs' case, and such a result is unduly harsh to Plaintiffs themselves who have had nothing to do with counsels' flagrant abuse of the discovery process and disregard of court orders.

The court has fashioned sanctions pursuant to Rule 37(b) and (c) which account for counsels' unacceptable conduct without unduly punishing Plaintiffs' for the transgressions of counsel. This court's power to fashion such sanctions is broad. The court has already discussed the nature its power to impose sanctions pursuant to Rule 37 of the Federal Rules of Civil Procedure. Underscoring this statutory authority is the court's inherent authority to impose sanctions for misconduct. As the Supreme Court observed in Chambers v. NASCO, Inc., 501 U.S. 32, 111 S.Ct. 2123, 115 L.Ed.2d 27 (1991):

> It has long been understood that "[c]ertain implied powers must necessarily result to our Courts of justice from the nature of their institution," powers "which cannot be dispensed with in a Court, because they are necessary to the exercise of all others." For this reason, "Courts of justice are universally acknowledged to be vested, by their very creation, with power to impose silence,

> respect, and decorum, in their presence, and submission to their lawful mandates." These powers are "governed not by rule or statute but by the control necessarily vested in courts to manage their won affairs so as to achieve the orderly and expeditious disposition of cases."

Id. at 43, 111 S.Ct. at 2132 (citations omitted). " 'By controlling an attorney's conduct, the court fulfills the duty it owes to its own preservation, to members of the general public, and to those members of the profession who do cooperate and are in sympathy with proper administration of the law.' " Grace v. Center for Auto Safety, 155 F.R.D. 591, 601 (E.D.Mich.1994) (footnote omitted). Because of the potency of the sanctions available, the imposition of sanctions is a matter that cannot be taken lightly by the court. Chambers, 501 U.S. at 44, 111 S.Ct. at 2132. Further, the court must exercise restraint in imposing sanctions. Id.

This court's January 5 order detailed the court's rationale for excluding certain "new" expert reports which Plaintiffs sought to file on the eve of the first round of in limine hearings. Upon publication of this order, there could be no question in the minds of Plaintiffs' counsel that continued filing of supplemental affidavits containing new methods and information, without leave of court, was prohibited. As such, the court will exclude from the record all supplemental affidavits filed after January 5, 1996.[13] Fed.R.Civ.P. 37(b)

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13. With respect to these filings the court finds the imposition of monetary sanctions upon counsel to be an ineffective sanction. Malautea v. Suzuki Motor Co., Ltd., 987 F.2d 1536, 1544 (11th Cir.1993) ("When lesser sanctions would be ineffective, Rule 37 does not require the vain gesture of first imposing these ineffective lesser sanctions.")

and (c). All supplemental affidavits and reports filed subsequent to the March 1, 1995 filing deadline but prior to January 5, 1996, and whose admissibility has not previously been ruled upon by this court, shall be admitted.[14] Additionally, the court will issue a separate order to show cause why monetary sanctions should not be imposed against certain of Plaintiffs' counsel. Counsel will be afforded the opportunity to respond at that time. Chambers, 501 U.S. at 50, 111 S.Ct. at 2136 (court must "comply with the mandates of due process, both in determining that the requisite bad faith exists and in assessing fees").

II. Defendants' Motion for Reconsideration of the Court's January 5, 1996 Memorandum as it Pertains to Vladimir Shevchenko

On January 22, 1996, Defendants filed the instant motion for reconsideration. The motion has been briefed by the parties and is ripe for disposition. "The purpose of a motion for reconsideration is to correct manifest errors of law or fact or to present newly discovered evidence." Harsco v. Zlotnicki, 779 F.2d 906, 909 (3d Cir.1985) (citation omitted),

14. To the extent that Defendants have not had the opportunity to depose an expert witness or cross-examine that witness at the in limine hearings as to a methodology that the court has now found to be admissible, Defendants will be permitted to promptly notify the court of the expert's name and the methodology at issue. The court reserves the right to revisit this issue upon receipt of such notification from Defendants. However, the court believes that Defendants have had the opportunity to depose or cross-examine Plaintiffs' experts as to all proffered testimony which the court has ruled to be admissible.

cert. denied, 476 U.S. 1171, 106 S.Ct. 2895, 90 L.Ed.2d 982 (1986). Therefore, a court may properly grant a party's motion for reconsideration in any of the following circumstances: "(1) the development of an intervening change in the law, (2) the emergence of new evidence not previously available, or (3) the need to correct a clear error of law or prevent a manifest injustice." Cohen v. Austin, 869 F.Supp. 320, 321 (E.D.Pa.1994) (citations omitted). Because Defendants have raised important, though not entirely availing, challenges to the court's January 5, 1996 ruling, the court will reach the merits of Defendants motion for reconsideration.

A. Dr. Snigiryova's Cytogenetic Analysis

Defendants contend that the court made a number of factual and legal errors in ruling on the admissibility of Professor Shevchenko's testimony regarding the Snigiryova cytogenetic analysis. The court will address these assignments of error seriatim.

1. Factual Error Regarding Hershey Medical Center Controls

Defendants argue that the court misapprehended certain hearing testimony to reach the erroneous conclusion that Dr. Snigiryova compared her study results with a Hershey Medical Center control group. Defendants and Plaintiffs agree that the court incorrectly identified the Hershey control group with the Snigiryova cytogenetic analysis rather than with Dr. Tarasenko's immune study. The court's review of the record indicates that the court did incorrectly associate

the Hershey Medical Center control group with the Snigiryova study. The issue then, is whether this factual error by the court alters its legal ruling with respect to the Snigiryova cytogenetic analysis.

In the January 5 ruling, this court noted the following:

> [W]ith respect to the proffered cytogenetic testimony, Defendants raise an issue related to the propriety of the control group. Defendants contend that the cytogenetic analysis is flawed because Professor Shevchenko and Dr. Snigiryova did not employ a contemporaneous and geographically proximate control group. . . . Plaintiffs did, however, present testimony which showed that the historical Russian controls used by Professor Shevchenko and Dr. Snigiryova had background dicentric counts virtually identical to those of a control group measured at Hershey Medical Center in Hershey, Pennsylvania. (Tr. at 705.) The court finds that Plaintiffs have come forward with sufficient evidence to demonstrate that their control group, while not contemporaneous and geographically proximate, is adequate.

In re TMI Cases Consolidated II, 911 F.Supp. 775, 816 (M.D.Pa.1996). The court must now determine whether, absent corroboration with a Pennsylvania control group, the control group utilized by Dr. Snigiryova was adequate. Defendants contend that Dr. Snigiryova's control sample was inadequate and improper. Plaintiffs, to the contrary, argue

that the literature supports the use of non-contemporaneous, geographically diverse control groups. Specifically, Plaintiffs refer the court to their in limine exhibit 72, Cytogenetic Study in Lymphocytes from Children Exposed to Ionizing Radiation After the Chernobyl Accident, 319 Mutation Research 55, 57 (1993) ("Chernobyl Accident"), and their in limine exhibit 73, Novel Biodosimetry Methods Applied to Victims of the Gioania Accident, 60 Health Physics 72, 75 (1994) ("Gioania Accident"). The court finds Plaintiffs reliance on these articles to be somewhat misplaced as the articles lend only tangential support to the argument that Plaintiffs advance.

The Chernobyl Accident study, which used a geographically diverse (Italian) control group in its cytogenetic analysis of Byelorussian children, noted the following:

> We are fully aware of the fact that these "control" children are characterized by a very different ethnic, life style, health, and dietary background. However, the problem could not be otherwise solved due to the circumstance that no children from other areas of Byelorussia were sent to Italy and that even their health and dietary conditions would have been different from those of the subjects analyzed. Unfortunately, no cytogenetic data concerning children from the same localities prior to the accident are available.

Id. at 57. This statement supports Plaintiffs argument insofar as it demonstrates that a scientific study, that relied on a

geographically diverse control group because a geographically proximate control was unavailable, was accepted for publication. The court, however, finds reliance on this study problematic.

First, Plaintiffs have placed no evidence on the record which tends to show that it was difficult or impossible for a geographically proximate control group to be utilized with respect to the instant study. Dr. Snigiryova's report, filed March 15, 1995, offers no explanation as to why she found it necessary to use Russian rather than American control values. It was only following Defendants' in limine challenge that Dr. Snigiryova filed a second report, dated September 25, 1995, that addressed the control issue. While Dr. Snigiryova's September report indicates that there is some support in the literature for her control values, the court cannot help but wonder whether this is merely a post hoc attempt to defend the methodology she employed. The court finds the issue of whether Dr. Snigiryova carefully considered the selection of an appropriate control group prior to beginning her study to bear directly upon the reliability of her methodology. Were she to have selected a control group because of time pressures related to this litigation, rather than because the group was scientifically the most appropriate control, such a selection would clearly flaw her methodology. A statement made by Dr. Snigiryova in her September report underscores this and other of the court's concerns:

> The aim of our work has not been to conduct extensive cytogenetic examinations of the population living in the neighborhood of TMI.

> Such work is time-consuming and expensive. The task facing us was to make a conclusion on the presence/absence of the action of radiation as a result of the accident at the TMI nuclear power station by comparing the level of cytogenetic disorders in the population from the examined region and in clinically healthy people living on [sic] the uncontaminated territory.

9/25/95 Snigiryova Rpt. at 1. Although Dr. Snigiryova's stated purpose was not to perform "extensive cytogenetic examinations," Plaintiffs seem to view her study somewhat differently. "Plaintiffs contend that the level of dicentrics in blood drawn from TMI residents, as determined by Dr. Snigiryova, is sufficiently high to conclude that accident exposures caused doses to these individuals in excess of 100 rems." (Pls.' Brief in Op. to Defs.' Motn. in limine to Exclude Pls.' Dose Experts at 164.) Dr. Shevchenko has taken a limited study whose purpose was merely to show the presence or absence of chromosomal aberrations, and used the findings to calculate a dose. As will be discussed below, this methodology is scientifically problematic. Moreover, it appears from the quoted statement that Dr. Snigiryova presumed that the TMI area was contaminated. Whether the TMI area was or is contaminated is a central issue in this lawsuit, and a question that has remained largely unanswered in the scientific community for nearly two decades. Accordingly, it would be highly inaccurate and seemingly unscientific to base a study upon the unproven assumption that the TMI area is or was contaminated.

Next, the Chernobyl Accident article undermines the validity of Professor Shevchenko's dose estimates based on

the cytogenetic study. The summary preceding the article indicates the following: "[d]ue to the very low fraction of dicentrics, because of the time elapsed from the accident and the relatively low doses of exposure, radiobiological dosimetry is not possible for these children." Id. at 55. The article goes on to attribute the presence of chromosomal aberrations to the fact that the children have likely been exposed to continuing low-level ionizing radiation remaining from the accident. Id. at 59. Thus, as much as this article may lend support to the notion that the use of geographically diverse control groups is proper under certain circumstances, it detracts support from the proposition that Professor Shevchenko or Dr. Snigiryova could make a reliable dose estimate based upon a cytogenetic analysis performed fifteen years after the alleged exposure to radiation.

The court's review of relevant scientific literature has produced no clear guidance as to whether contemporaneous and geographically proximate control samples are essential to a scientifically reliable study. The International Chernobyl Project studies conducted in the aftermath of the Chernobyl accident included dicentric chromosome analyses. Findings of those studies showed that "[t]he frequency of aberrations in control areas was surprisingly high. . . . Reasons for this high frequency are unclear; however, the background rate of aberrations among different populations has been shown to be variable. Future studies on this subject are certainly worthwhile." International Advisory Committee Technical Report, The International Chernobyl Project 298 (IAEA 1991) (emphasis added). This statement seems to be representative of present scientific opinion on this issue. Thus, the court is placed in the uncomfortable position of

making a determination as to the propriety of a particular scientific methodology where the relevant scientific community has yet to reach agreement on that very issue.[15]

Based upon the foregoing, the court must find that the failure to use a contemporaneous, geographically proximate control group goes to the weight of Professor Shevchenko's testimony. This finding is rooted in the court's interpretation of the relevant scientific literature. The court reads this literature to recommend the use of contemporaneous and geographically proximate control groups; however, the court does not find that the absence of such control groups renders a study invalid per se. Defendants motion for reconsideration will be denied as to this narrow issue. While the court has found that the choice of control groups has not in itself rendered the cytogenetic analysis scientifically unreliable, the court will discuss below certain aspects of the proffered testimony that the court, upon review, has found to be scientifically unreliable.

2. Errors of Law

Defendants contend that the court made several legal errors in evaluating the admissibility of Dr. Snigiryova's cytogenetic analysis. Specifically, Defendants argue that the court erred in ruling that Professor Shevchenko's testimony is admissible in light of the following: (1) pursuant to Paoli

15. Plaintiffs' would argue that this is the type of factual determination that should be made by the jury, not the court. As uncomfortable as it may be for the court to make this determination, the court would abdicate its role as gatekeeper by passing this decision on to the jury.

II, any step that renders the expert's methodology unreliable renders the testimony inadmissible, therefore, Dr. Snigiryova's failure to employ an appropriate control group renders testimony regarding the cytogenetic analysis inadmissible; (2) Dr. Snigiryova's failure to employ the FISH method in her dose reconstruction renders her methodology hopelessly flawed and thus inadmissible; and, (3) the court reached improper conclusions based upon its analysis of several of the Paoli II factors. The court's discussion above refutes Defendants' first assignment of error. Discussion of the remaining arguments is necessary.

a. The Fluorescence In Situ Hybridization Technique

The scientific literature pertaining to use of cytogenetic analysis as a method of dose reconstruction supports the proposition that dose reconstruction through cytogenetic analysis becomes less accurate and effective as time progresses following the date of exposure. See, e.g., National Research Council, Radiation Dose Reconstruction 59 (National Academy Press 1995) ("Radiation Dose Reconstruction") ("[A]mong the most sensitive markers for radiation exposure is the enumeration of unstable chromosome aberrations. If this marker is measured within a year after exposure there will be little decay and the sensitivity will allow it to serve as a good dosimeter.") The decline in effectiveness as time passes arises because unstable chromosome aberrations disappear over time. Dr. Snigiryova explained in her report that the number of chromosome aberrations will decrease by approximately fifty percent within three to five years following exposure to

ionizing radiation. 3/15/95 Snigiryova Rpt. at 1, 7-8. Recently, a technique known as fluorescence in situ hybridization ("FISH") has been developed. The FISH method is more effective than traditional cytogenetic analysis in reconstructing dose when significant time has elapsed since the date of exposure. Radiation Dose Reconstruction at 59 ("The disadvantages associated with unstable markers are avoided when stable markers, such as reciprocal translocations measured by fluorescent in situ hybridization, are used.") The method has been described as follows:

> In this technique, the DNA is thermally denatured to provide single strands of DNA. These targeted strands are incubated with nontarget DNA probes that bind to the DNA sequences that are homologous. The target DNA is stained, and the nontarget DNA is counterstained. Under a fluorescence microscope the target DNA appears yellow, and the nontarget DNA appears red. In the case of a translocation, the affected DNA strand will appear to be partially red and partially yellow. This method detects only a fraction of the translocations, so that it is necessary to apply a multiplication factor to estimate total translocation frequency.

(Defs.' Ex. 155 (Fred A. Mettler, Jr., M.D. and Arthur C. Upton, M.D., Medical Effects of Ionizing Radiation 65 (2d ed. 1995).)) Defendants' contend that the court erred in finding Dr. Snigiryova's cytogenetic analysis to be scientifically reliable despite the fact that the court recognized that "[Professor] Shevchenko failed to employ

the only recognized method for performing dose reconstruction through a cytogenetic method after a long lapse of time." (Defs.' Brief in Supp. of Motn. for Reconsid. at 7.) Plaintiffs' claim that Professor Shevchenko did perform a "supplemental verification" of the results of the cytogenetic analysis using the FISH method. Further, Plaintiffs argue that because the court prohibited testimony on this issue at the in limine hearings, the court cannot now base its finding on a lack of record evidence as to this issue.

This issue highlights the problems that the court has encountered in dealing with Plaintiffs' continual "supplemental" reports. The court prohibited testimony on the FISH method at the hearings based upon its finding that the timely filed expert reports of Professor Shevchenko and Dr. Snigiryova did not contain any substantive discussion of a utilization of the FISH method to verify the results of Dr. Snigiryova's cytogenetic analysis. Dr. Snigiryova's discussion of the FISH method in her initial report was confined to the following statements:

> The problem of the estimation of dose radiation using the cytogenetic data is very problematically [sic] in this situation. Firstly [sic] this is connected with a long period after TMI accident. In such situation it seems necessary to estimate stable chromosome aberration in lymphocytes of peripheral blood, using FISH method. . . .

3/15/95 Snigiryova Rpt. at 8. She again briefly raised the issue in response to an in limine challenge by Defendants. 2/25/95 Snigiryova Rpt. at 6 ("More detailed information

about these people will come from the analysis of frequency of stable translocations using FISH method."). Professor Shevchenko's 2/21/95 "Final" Report briefly alluded to the FISH method as follows:

> The problem of estimation of an absorbed dose on the basis of results of cytogenetic analysis is important. The lymphocytes with unstable chromosome aberrations (dicentrics and rings are referred to this group) are gradually goes out [sic] from peripheral blood because of a renovation of a pool of lymphocytes. . . . The latter figure follows from a ratio between unstable (dicentrics and rings) and stable (translocations) chromosome aberrations revealed by FISH-method. . . . Unfortunately so far we don't know a ratio between stable and unstable chromosome aberrations for persons suffered from TMI accident. . . .

2/21/95 Shevchenko Rpt. at 6-7. In his October 6, 1995 report, filed in response to Defendants' in limine challenge, Dr. Shevchenko indicated "[t]he dose estimate of 0.6-2 Gy for this group given in my Final report of February 21, 1995 can be defined more exactly after a cytogenetic analysis of stable chromosome aberrations using the FISH-method." 10/6/95 Shevchenko Rpt. at 22.

The evidence before the court demonstrates that the number of unstable chromosome aberrations decrease over time. The evidence further shows that cytogenetic analysis

is a reliable means of reconstructing dose when done shortly after the time of exposure; and, that the FISH method is an accurate means of reconstructing dose when longer time periods have elapsed since exposure. Plaintiffs' experts conducted a traditional cytogenetic analysis on blood samples collected from TMI residents. These blood samples were taken approximately fifteen years after the alleged exposure. Both Dr. Snigiryova and Professor Shevchenko state in their reports that this time lapse is problematic in the context of reconstructing a dose. Both experts also agree that the TMI blood samples should be analyzed using the FISH method to obtain an accurate dose estimate. Contrary to the record evidence, Plaintiffs argue that their experts can quantify the dose of ionizing radiation allegedly received by TMI residents based solely upon the traditional cytogenetic analysis performed fifteen years after the presumed date of exposure.

In its January 5 ruling, the court weighed Professor Shevchenko's failure to utilize the FISH method in favor of excluding the proffered testimony. In re TMI, 911 F.Supp. at 813. Nevertheless, based upon the balance of its analysis, the court ultimately found the proffered testimony to be admissible. Id. at 816-17. In making this determination, the court relied heavily on Professor Shevchenko's vast experience. Defendants have directly challenged this ruling. Upon reconsideration, the court finds that it erred in ruling that Professor Shevchenko's dose estimates derived from the cytogenetic analysis are admissible. While the court believes that his experience is still directly relevant to his tree study methodology, the court improperly accorded too much

weight to this factor with respect to the cytogenetic analysis.[16] The record evidence is uncontroverted. The FISH method is the procedure employed by scientists to accurately reconstruct dose when prolonged periods of time have elapsed since exposure.

Neither Professor Shevchenko nor Dr. Snigiryova analyzed the TMI blood samples using the FISH method prior to the November 1995 in limine hearings. Their reports indicate that they are presently re-analyzing the blood samples using the FISH method, and that these results will validate their findings from the general cytogenetic analysis. This argument distorts the letter and spirit of the Federal Rules of Civil Procedure beyond recognition. Final reports of Plaintiffs' dose experts, containing a complete statement of the methodologies employed and the basis for the opinions, were due March 1, 1995. Had Plaintiffs produced the actual findings of a study using the FISH method on the TMI blood samples at the November in limine hearings, the court would likely have admitted those findings and allowed

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16. The record before the court demonstrates that Professor Shevchenko's experience is with evaluating the cellular and subcellular effects of ionizing radiation on trees. Further, the court is satisfied that Professor Shevchenko has, through the course of his work in the Soviet Union, observed the morphological effects of ionizing radiation on trees. The court has accorded significant weight to this experience for the purpose of evaluating Professor Shevchenko's tree study. The record does not reflect a similar level of expertise or professional experience in interpreting the results of a cytogenetic analysis. As such, the court was incorrect in finding Professor Shevchenko's practical experience to weigh heavily in its analysis of the scientific reliability of the dose estimates derived by Professor Shevchenko based upon the cytogenetic analysis.

Defendants wide latitude to cross-examine.[17] That Plaintiffs only recognized the importance of conducting the FISH analysis after the filing deadlines passed is not sufficient justification for admitting such evidence one year after the filing deadline and four months after the in limine hearings on dose concluded.

Based upon the foregoing, the court will grant Defendants' motion for reconsideration with respect to Professor Shevchenko's dose estimates. While Professor

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17. The court precluded Professor Shevchenko from offering general testimony regarding the FISH method at the in limine hearings because such testimony was beyond the scope of his timely filed report. It is the court's understanding that Professor Shevchenko was unable to discuss the results of a FISH analysis being performed on the TMI samples because that analysis was not yet complete. The following exchange occurred between Plaintiffs' counsel and the court:

> I think with validation of reliability at issue . . . that it is appropriate for him to at least discuss why he has confidence in the reliability of his opinion with respect to his regression analysis for the dicentric counts.
>
> THE COURT: How can . . . [Defense counsel] cross-examine him on the FISH method when he doesn't have a report on it?
>
> MR. BERMAN: That is a good question, Your Honor.
>
> THE COURT: Sustain the objection.

(11/22/95 Tr. at 1146.)

Shevchenko will be permitted to testify as to the cytogenetic analysis performed and as to the findings regarding the presence or absence of chromosome aberrations, Professor Shevchenko will not be permitted to give a quantified dose estimate based upon the cytogenetic analysis. The court finds that the methodology employed by Dr. Shevchenko to arrive at his dose estimate is scientifically unreliable when performed fifteen years after the alleged exposure to radiation.

B. Professor Shevchenko's Tree Study

Stated in the most general terms, Defendants challenge the court's ruling as to the admissibility of the Shevchenko tree study testimony is centered upon their assertion that his methodology was scientifically unreliable. Defendants point to Professor Shevchenko's contradictory testimony as to whether he performed a differential diagnosis or examined a control group as evidence that he manufactured the "proper" methodology in response to Defendants' in limine challenge. A recent Third Circuit opinion reiterates the standard pursuant to which Professor Shevchenko's tree study must be evaluated:

> Under Daubert's interpretation of Rule 104(a), a district court facing a proffer of scientific expert testimony must as a preliminary matter assess whether the reasoning or methodology underlying the expert's testimony is scientifically valid. The court accomplishes this "by considering all relevant factors that may bear on the reliability of the proffered evidence. The reliability

> requirement, however, should not be applied too strictly. Helpfulness to the trier of fact remains the ultimate touchstone of admissibility. If the expert has "good grounds" for the testimony, the scientific evidence is deemed sufficiently reliable. A determination that the expert has good grounds assures that the expert's opinions are based on science rather than "subjective belief or unsupported speculation."

Holbrook v. Lykes Bros. Steamship Co., No. 94-2148, slip. op. at 14, 80 F.3d 777, 784 (3d Cir.1996). Defendants' criticism of Professor Shevchenko's study is accurate and insightful. The court, however, finds that exclusion of the proffered testimony on the grounds urged by Defendants would amount to an overly strict application of Daubert. Despite Defendants' argument to the contrary, the court continues to find Professor Shevchenko's experience and expertise to be extremely relevant to the overall analysis of his proffered tree study testimony. As the court noted in its January 5 ruling, "[l]ikely more than any other expert before the court, Professor Shevchenko has had extensive first-hand experience examining the effects of radiation exposure." In re TMI, 911 F.Supp. at 817. Because of his extensive first-hand experience, Professor Shevchenko's observations will be helpful to the trier of fact. Even if Professor Shevchenko were to do nothing more than to verify that he observed radiation damaged trees in the former Soviet Union, and note that the damage he saw in the TMI area was consistent with his observations of tree damage in the former Soviet Union, his testimony would assist the jury in determining whether it is more likely than not that the TMI

area was contaminated during the TMI accident. Thus, the court will affirm its prior ruling that Professor Shevchenko's general testimony regarding his comparison of tree damage in the TMI area with tree damage in radiation exposed areas of the former Soviet Union is admissible. Defendants' motion for reconsideration will be denied as to this portion of Professor Shevchenko's proffered testimony.

A more difficult question raised by Defendants' motion is whether the court properly admitted Professor Shevchenko's dose estimates based upon the tree study. To rule on this motion, the court again reviewed Professor Shevchenko's deposition and hearing testimony, specifically noting the inconsistencies raised by Defendants. This review indicates that Defendants are correct in their observation that Professor Shevchenko's testimony has changed over time in response to challenges made by Defendants. Most troubling to the court is a statement made by Professor Shevchenko in his February 4, 1996 affidavit.[18] In attempting to refute challenges made in Defendants' motion for reconsideration, Professor Shevchenko argued that his control sample was proper, inter alia, because "according to the data from the Hershey Medical Center, the same level of chromosome aberrations has been observed in this region in the control groups as in our control materials." 2/4/96 Shevchenko Aff. at 3. This is the very data that the court wrongfully attributed to the cytogenetic analysis. Based upon this statement, it is clear that Professor Shevchenko lacks knowledge of what control groups were actually employed in the Snigiryova cytogenetic analysis. To the extent that this statement

18. The court admits this affidavit solely for its use in the present discussion.

identifies a possible lack of candor with the court on the part of Professor Shevchenko, the court finds that such is a credibility determination for the jury.

More important for the court at this juncture is what the statement reveals about Professor Shevchenko's methodology for both his tree study an his cytogenetic analysis. Each time Professor Shevchenko offers testimony, whether in a hearing, deposition, report, affidavit or letter, a component of his methodology changes. The most certain thing that the court can say regarding the dose calculations derived from the tree study methodology is that after reading all Professor Shevchenko's reports, deposition testimony, and the hearing transcripts, the court is unable to define the precise steps of his methodology. Each time Professor Shevchenko states his methodology Defendants challenge a component of that methodology and Professor Shevchenko alters the methodology to rebut the challenge. It is axiomatic that such methodological fluctuations are not scientific. Daubert and Paoli II direct this court to apply liberally the reliability prong of Rule 702 to allow admission of testimony based upon good grounds that will be helpful to the trier of fact. A proportedly scientific opinion that constantly changes merely to avoid critique can hardly be said to be based upon "good grounds." Moreover, the court is unable to find that Professor Shevchenko's vascilating methodology and opinions based thereon will assist the jury in making a determination on any fact in issue.

Based upon the foregoing the court will grant Defendants' motion for reconsideration and reverse its prior ruling with respect to Professor Shevchenko's quantitative

dose estimates derived from his tree study analysis. Professor Shevchenko will still be permitted to testify as to the observations he made of damaged trees in the TMI area and as to his comparison of the damage observed here with tree damage at radiation exposed sites in the former Soviet Union.

III. The Wing Rate of Error Issue

A. Background

In its January 5 opinion, the court deferred ruling on the admissibility of the Wing cancer incidence study pending further briefing on the rate of error issue. The court found that it was unprepared to make a final ruling on that issue based upon the evidence and briefing before it. Supplemental briefing on the rate of error issue is complete, and the court is now prepared to rule on the admissibility of the Wing cancer incidence study. At the outset, the court must comment on Plaintiffs' approach to the supplemental briefing. According to Plaintiffs' brief, "to respond to . . . [the court's request], plaintiffs provided Dr. Wing with a copy of the portion of the Court's January 5, 1996 Memorandum that addresses Dr. Wing's testimony, opinions and reports . . . and have asked Dr. Wing to respond to the Court's directive." Had the court wished to hear further testimony on this issue from Dr. Wing, the court would have directed him to submit an affidavit.[19] Moreover, had the court

19. In fact, on March 27, 1996, the court contacted Plaintiffs' counsel and requested that Dr. Wing reword in "laymen's terms" four paragraphs of the "statistical methods" section of his February 25, 1995 report. The court was not confident of its understanding of

(Cont'd)

wanted Dr. Wing to calculate the confidence intervals for his study based upon values that he previously reported, the court likewise would have made such a request. The method that Plaintiff has employed to respond to the court's request for further briefing is emblematic of the way they have responded to Defendants' challenges to their expert testimony. Additionally, it is the root cause of much of the difficulty that the court has encountered in evaluating Plaintiffs' experts' proffered testimony.

It is necessary to state what the court believed to be the obvious. In its January 5 order, the court directed Plaintiffs' counsel to provide a more concise discussion of the rate of

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some of the terminology in this section (e.g. "The models were fit with Poison regression using the GLIM statistical package." Id. at 6.), and felt strongly that a complete understanding of this section was important to its analysis. The court is in receipt of Dr. Wing's statement, and is grateful for his assistance in clarifying this section of the report.

With respect to this request for clarification, the court was disappointed to find that despite its correspondence with Plaintiffs' counsel requesting that they refrain from making personal attacks on the court in their filings, Plaintiffs' counsel have elected to continue with this unnecessary and unprofessional practice. (Pls.' Supplemental Filing Provided By Plaintiffs' Expert Dr. Steven B. Wing in Response to Court Request at 1 ("The Court's clerk advised plaintiffs' counsel that the reason the court desired an explanation by Dr. Wing is that the Court is not sophisticated in and knowledgeable about statistical terminology, and therefore, the Court desired that the four paragraphs be explained in language which the Court, as a lay person, might be able to understand.").) The court takes this opportunity to again stress that it frowns upon this practice.

error calculations performed by Dr. Wing during the cancer incidence study. The court did not grant Plaintiffs leave to augment the cancer incidence study. For the purposes of this litigation, the court is not interested in what Dr. Wing might have done if he had more time, what he will do in future studies, or what he would do if he were permitted to change his methodology in response to Defendants' criticism. The court, on the other hand, is very interested in better understanding what Dr. Wing did do when conducting the initial cancer incidence re-analysis. The critical issue presently before the court is whether Dr. Wing made an effort to determine the known or potential rate of error for his study. Plaintiffs have argued in their briefing and presented some evidence at the hearings that Dr. Wing eschews the traditional confidence interval method for calculating error and instead uses another approach. It was the court's inability to completely understand the nature of this "other approach" apparently utilized by Dr. Wing which led the court to order further briefing on the issue. In re TMI, 911 F.Supp. at 822 ("the court is cognizant that part of the difficulty in resolving this factor is due to the court's own uncertainty regarding Dr. Wing's standard error calculations . . . the court will order Plaintiffs to provide a more direct and substantiated discussion of the error issue"). Unfortunately, rather than taking this opportunity to further educate the court as to their experts' methods, Plaintiffs have used their rate of error brief to criticize the court for its "emphasis" on the rate of error issue.

In their brief, Plaintiffs argue that "Dr. Wing did not calculate the rate of error for his reanalysis for philosophical reasons relating to the scientific purpose of epidemiological

studies." (Pls.' Rate of Error Brief at 3.) Plaintiffs contend that Dr. Wing's October 19, 1995 affidavit provides a full explanation of this issue. The October 19 affidavit presents problems in its own right as it is a supplemental report, filed more than six months after the discovery deadline in response to Defendants' in limine challenge, which alters Dr. Wing's methodology. As discussed in § I, supra, the court has grounds to strike this affidavit pursuant to Rules 26 and 37 of the Federal Rules of Civil Procedure. Nevertheless, because the court finds it important to provide a substantive analysis of the rate of error issue, the court will consider the affidavit for the purposes of its analysis.

B. Discussion

Dr. Wing's explanation of his decision not to perform statistical significance testing on his cancer re-analysis is as follows:

> Abuse of significance testing in epidemiological research is now widely appreciated and discussed. The problem is clearly recognized by one of the defense's experts, K. Rothman, who wrote in an editorial introducing a paper on logical problems with statistical significance testing, "In a century in which science has reveal that molecules an atoms are mostly unoccupied space and that matter is energy anyway, we should be accustomed to having the substance of our scientific foundations dissolve into emptiness. In this issue [of the journal], Greenland perforates the foundations of statistical interpretations used

> by epidemiologists in just this way." The problems with significance testing . . . have been recognized for some time, but have been ignored in the interests of preserving a simple if fallacious method that was inconclusive or spurious. . . . "Greenland shows us that, despite our reliance on conventional statistics for interpreting our nonexperimental results, there is no basis for the interpretations usually given to these statistics in nonexperimental settings." This is because, in the absence of randomization of exposure in a fair experiment, it is not possible to distinguish the extent to which test statistics reflect bias or the exposure under investigation.
>
> (B.) For this reason we do not present tests of statistical significance, although they can be calculated based on figures given in the report. Our preference, and one increasingly being recognized as a responsible scientific approach, is to evaluate the statistical evidence in the context of the sensitivity of the findings to changes in assumptions and data, coherence of the evidence with other knowledge, the magnitude of associations, their consistency across groups, and temporal relationships of exposure and effect.

10/19/95 Wing Aff. at 3 (emphasis in Wing Aff.). Based upon this explanation, the court is left to determine whether Dr. Wing's method in evaluating the statistical evidence provides an accurate measure of the known or potential rate of error in his cancer re-analysis. To make this determination,

the court must perform a Daubert-like analysis to ascertain whether the method employed by Dr. Wing in calculating the rate of error is scientifically reliable.

The rate of error issue is important to Dr. Wing's reanalysis because it assists the court in identifying what inferences can be drawn from his findings. Specifically, a rate of error calculation will help to define the degree to which his findings might be due to random error rather than a causal relationship between radiation exposure from TMI and an increased cancer incidence. To the extent that the results are more likely the product of random error than a true causal relationship, the probative value of the study necessarily decreases. Traditional methods of establishing the rate of error in a study are through the use of standard errors, confidence intervals, and p-values.[20]

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20. The Reference Manual on Scientific Evidence defines these terms as follows:

> Standard Error (SE). Indicates the likely size of the sampling error in an estimate. Many authors use the term "standard deviation" instead of standard error.
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> Confidence Interval. An estimate, expressed as a range, for a quantity in a population. If an estimate from a large sample is unbiased, a 95% confidence interval is the range from two standard errors below to two standard errors above the estimate. Intervals obtained this way cover the true value about 95% of the time, and 95% is the confidence level, or the confidence coefficient.
>
> p-Value. The output of a statistical test. The probability of getting, just by chance, a test statistic as large as or

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Appendix E

Rather than employing one of these standard methods, Dr. Wing opted for a less mathematical approach which "evaluate[s] the statistical evidence in the context of the sensitivity of the findings to changes in assumptions and data, coherence of the evidence with other knowledge, the magnitude of associations, their consistency across groups, and temporal relationships of exposure and effect." 10/19/95 Wing Aff. at 3. Dr. Wing states that he uses this methodology because of his belief, a belief he argues is shared by other epidemiologists, that statistical significance testing is often employed in a dishonest fashion. The court is in agreement with Plaintiffs that there is presently an ongoing dialogue within the relevant scientific community on the issue of significance testing. See, e.g., S. Greenland, "Randomization, Statistics and Causal Inference," 1 Epidemiology 421 (1990). Moreover, the court is aware that the debate has carried over into the judicial arena. The court does, however, differ with Plaintiffs' as to the nature of the dialogue. The court's review of the literature, including the Greenland article, suggests that the focus of the debate is on the weight to accord significance testing when evaluating a study, rather than the

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> larger than the observed value. Large p-values are consistent with the null hypothesis; small p-values undermine this hypothesis. However, p itself does not give the probability that the null hypothesis is true. If p is smaller than 5%, the result is said to be statistically significant. If p is smaller than 1%, the result is highly significant. The p-value is also called the significance level.

Ref.Man. at 409, 396, 402.

question of whether significance testing should be used in the first place. See Ref. Man. at 153-54 & n. 82 (citing cases demonstrating the split amongst federal courts on this issue).

Contrary to the presumption made by Plaintiffs' in their brief, the issue for the court has never been whether Dr. Wing's study produced statistically significant results, whether he calculated 95% confidence intervals, or whether the p-value was 0.5. (Pls.' Rate of Error Brief at 7) ("Since the Third Circuit has not stated a rule of law that a magical level of significance must be shown before an epidemiological study is admissible, Dr. Wing's report and testimony focused more on the helpfulness that his analysis would have to the trier of facts rather than seeking to quantify the rate of error as though such an exercise would have magical significance.") Pursuant to Daubert and Paoli II this court is required to make an inquiry regarding the known or potential rate of error of any scientific evidence placed before the court. As this court interprets the legal precedent, the inquiry entails making a determination as to whether the known or potential rates of error are so high as to affect the scientific reliability of the evidence. Neither Daubert nor Paoli II require that a scientist use traditional methods for assessing the known or potential rate of error in their study. Nevertheless, Daubert and Paoli II do impose an obligation upon the party proffering the expert testimony to present to the court, in a manner in which the court or a jury can readily understand, some evidence of the known or potential rate of error. Further, this court reads Daubert and Paoli II as suggesting that the ascertainment of a known or potential rate of error by the proffered expert is an important indicia of the scientific reliability of the study. Thus, while a

coherent articulation by Plaintiffs of Dr. Wing's rate of error methodology would not have "magical significance," it would go a long way toward assisting this court to properly exercise its gatekeeping function.

Plaintiffs' brief fails to provide the discussion expressly requested by the court. Since the court requested the additional briefing, Plaintiffs have filed four new affidavits of Dr. Wing, each of which expand upon his timely filed report. 1/12/95 Wing Aff. ("This affidavit responds to the request for clarification of issues related to the 'known or potential rate of error' "); 1/16/95 Wing Aff. ("This affidavit addresses two issues raised in Judge Rambo's Memorandum of January 5, 1996"); 1/31/96 Wing Aff. ("In previous affidavits to the Court I have attempted to make clear the substance and methods of our research on incidence of cancer following the accident at TMI . . . Despite previous work and explanations of methods and results, questions continue to be raised about the scientific work, with the implication that it is biased by our connection with plaintiffs in the case."); 2/7/96 Wing Aff. ("The following graphs present age adjusted cancer incidence trends for the Three Mile Island 10-mile area and comparison rated from the National Cancer Institute's Surveillance, Epidemiology and End Results (SEER) survey.") As the court explained above, Dr. Wing has submitted a formal report and testified at the in limine hearings. The scope of his opinion, for the purposes of this litigation, has been defined. It is understandable that Dr. Wing, who has expended significant effort to conduct a re-analysis of the Susser/Hatch data, would want to vigorously defend his study. This is the way that science evolves in the scientific community. Unfortunately, this is

not the way scientific testimony is presented in a court of law. Plaintiffs' counsel bore the burden of relaying this distinction to their experts and explaining the way that the court must deal with scientific evidence, regardless of how preposterous the legal methods may seem to a scientist. It is the role of Plaintiffs' counsel, who are well versed in the intricacies of the law, to craft arguments in response to legal challenges raised by Defendants. Dr. Wing's role in this litigation is to provide expert testimony regarding the methodology and findings of the studies he conducted, not to provide legal arguments in response to issues raised in Defendants' filings or the orders of this court.[21]

Insofar as they may be relevant to the instant rate of error discussion, the court will not consider any affidavit filed by Dr. Wing in the aftermath of the November in limine hearings.[22] Plaintiffs did not seek and therefore were not granted leave of court to supplement Dr. Wing's report or hearing testimony, and Defendants will have no opportunity to conduct discovery with respect to these untimely filings prior to trial. The court is unwilling to modify the pre-trial schedule and move the trial date to afford Defendants the time to adequately review these late filings. The court will consider untimely affidavits filed prior to the commencement of the November in limine hearings to the extent that Defendants had the opportunity to explore these affidavits with Dr. Wing during the hearings.

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21. Of course, this is not to imply that it would be improper for Dr. Wing to provide technical support to Plaintiffs' counsel and advise them on the scientific aspects of their arguments.

22. Excepted from this ruling is the filing that the court requested Plaintiffs to make on March 29, 1996.

Appendix E

The court will approach the rate of error question by examining only the alternative error ascertainment methodology which Dr. Wing claims to have used in conjunction with the timely filed portion of the cancer incidence study. Defendants argue that application of the factors which Dr. Wing deems relevant leads to the conclusion that there is a high rate of error inherent in his re-analysis of the Susser/Hatch data. Specifically, Defendants contend that: 1) contrary to what Dr. Wing testified would be proper, the risk ratios for leukemia incidence do not increase consistently from low dose unit study tracts to higher dose unit study tracts; 2) insofar as Dr. Wings results show an accident related increase of "all cancers" and lung cancer, his findings lack coherence with the known 10 year minimum latency period for solid tumors; and 3) with respect to the "magnitude of associations" factor, Dr. Wing fails to explain how such a large increase in lung cancer is associated with a much smaller increase in "all cancers" (one would expect to see an increase in "all cancers" that corresponds with the increase in lung cancer). (Defs.' Rate of Error Brief at 6-8.)

Upon further review of the Wing re-analysis, the court finds Defendants' argument with respect to the rate of error issue to be compelling. Accordingly, this factor will weigh in favor of the exclusion of the proffered testimony. Prior to its resolution of the rate of error issue, the court found that "[t]he Daubert/Paoli II analysis militates slightly in favor of admitting the proffered testimony." In re TMI, 911 F.Supp. at 823. Factoring the rate of error issue into this analysis, the court finds the Wing re-analysis to be only marginally scientifically reliable. Nevertheless, marginally scientifically reliable is not unreliable. Thus, vigorous cross-examination, rather than exclusion is proper.

Appendix E

Subject to the exclusions made in this court's November 9, 1995 order regarding Dr. Wing's "new graphs" and the January 5, 1996 memorandum and order regarding the lung cancer testimony, the court will admit the timely filed (2/25/95) Wing cancer incidence study. The court will narrowly construe this ruling. The scope of Dr. Wing's testimony will be limited to the contents of his timely filed report, his deposition testimony, and his testimony at the in limine hearing (to the extent that that testimony was not excluded by the January 5 order).

IV. Defendants' Motion in limine to Exclude Plaintiffs' Medical Causation Experts

On February 12-16 and March 1, 4-5, 1996, the court conducted a "second round" of in limine hearings in the captioned action. These hearings centered upon Plaintiffs' medical causation experts, but also included certain of Plaintiffs' dose experts who were unable to be present during the "first round" of in limine hearings. The court will evaluate the proffered testimony of each of the challenged dose and medical causation experts pursuant to the Daubert/Paoli II analysis set forth in this court's memorandum of law dealing with Defendants' in limine challenge to Plaintiffs' dose experts. In re TMI, 911 F.Supp. at 786-88.

A. Dr. Olga Tarasenko

Dr. Tarasenko is a physician and immunologist who is proffered to testify as to the results of an immunological study that she performed upon the blood samples of certain TMI area residents. The report of Dr. Tarasenko was initially

presented to the court as a component of Professor Shevchenko's report. Through an order dated November 9, 1995, the court prohibited Professor Shevchenko from testifying as to the methodology and results of the Tarasenko study as the court found Dr. Shevchenko unqualified to opine as an expert in immunology.[23] The court further ruled that Plaintiffs could proffer the Tarasenko report at the in limine hearings provided that Dr. Tarasenko was produced to offer that testimony. Due to circumstances beyond Plaintiffs' control, Dr. Tarasenko was unable to attend the first round of in limine hearings. The court permitted Dr. Tarasenko to offer her dose testimony at the most recent round of medical causation in limine hearings.

Dr. Tarasenko performed an immune study on blood samples of selected TMI area residents at the request of Dr. Snigiryova and Professor Shevchenko. (Tr. at 473 ("I received a phone call from Dr. Snigiryova. This doctor called me . . . and asked would it be possible to conduct . . . an analysis of blood samples by request of Dr. Shevchenko.").) She was provided with a portion of the blood samples that were initially provided to Dr. Snigiryova for her cytogenetic analysis. (Tr. at 520.) According to her report, Dr. Tarasenko conducted a "[c]omparative analysis of immune status characters of persons presumably subjected to ionizing radiation during [sic] TMI accident (group 1),

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23. The court found that Dr. Shevchenko lacked the technical knowledge to comment upon the methodology that Dr. Tarasenko employed in conducting her immune study. Because of his inability to discuss the technical nuances of the study methodology, the court found that Defendants' would be denied the opportunity to vigorously cross-examine regarding the immune study methodology.

persons participated [sic] in liquidation of consequencies [sic] of Chernobyl accident in 1986 (group 2), control group 3 (Moscow inhabitants), inhabitants of Muslumovo village from South Ural (group 4), inhabitants of a "clean" village of Altai region (group 5) was carried out." 2/15/95 Tarasenko Rpt. at 1. Through her study, Dr. Tarasenko "determined immunological parameters both to cellular immunity and to humoral immunity."[24] (Tr. at 479.) The general purpose of the Tarasenko study was to determine whether the TMI residents exhibited immune system depression, and if they did, to compare their immune system parameters with the immune system parameters of persons in the former Soviet Union who had been exposed to ascertainable doses[25] of ionizing radiation.

Dr. Tarasenko's findings were as follows:

> In . . . group [one] even average characters substantially differ not only from generally accepted levels of immunocompetent cells but from the levels obtained in control groups. . . .
>
> A sharp disbalance of immunoregulating cells was revealed. This disbalance in combination with the

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24. The term "humoral immunity" refers to non-cellular immunity. (Tr. at 479.)

25. Dr. Tarasenko testified that, with one exception, the twenty Chernobyl liquidators comprising group two of the study were exposed to approximately 25 rems of ionizing radiation. (Tr. at 514, 529-31.) The Muslumovo residents who comprised group 4 were known to have been exposed to up to 100 rems of ionizing radiation. (Tr. at 510, 530.)

> disturbances mentioned above evidences the presence of mixed immunodeficite [sic] status in the persons of group 1.
>
> Such disturbances are observed in the patients who use immunodepressants (widely used antibiotics, aspirin and other medicines can be referred to this group of chemicals) and suffer from cancer, autoimmune diseases, syndrom [sic] of chronic weariness and others. It is undoubtedly necessary to carry out a dynamic examination of all persons of this group, regular observation of their immune status, medical and prophylactic measures.

2/15/95 Tarasenko Rpt. at 2. Attached to the report are ten tables, unaccompanied by explanatory text, which set forth the statistical or mathematical results of Dr. Tarasenko's comparative study. 2/15/95 Tarasenko Rpt. tables 1-10. At the hearing, Dr. Tarasenko provided detailed and often confusing testimony regarding the meaning of these tables. (See generally, Tr. at 486-87, 496-515, 556-70.) According to Dr. Tarasenko, following the submission of her report, which contains no discussion of possibility or probability that the immune parameters observed in the TMI group were induced by radiation, she discussed her findings with Professor Shevchenko. (Tr. at 523.) Dr. Tarasenko testified that she "told to [sic] Dr. Shevchenko that such changes are possible as a result of the effect of eradiation [sic] and of a considerable magnitude, doses similar to those that were received by inhabitants of Muslumovo village and also by inhabitants in Altai." (Id.) In addition, Dr. Tarasenko noted

that the results of her study were transmitted to Professor Shevchenko prior to the time that she received data regarding the TMI group's medical history. (Tr. at 524.) After studying this medical data, Dr. Tarasenko claims to have been able to rule out the other possible causes of observed immune parameters which she had referred to in her report. (Id.)

The evidence before the court regarding the Tarasenko study is also somewhat confusing. Dr. Tarasenko's report, filed with this court on 3/15/95 as part of the Shevchenko report, does not indicate that she made any findings as to whether radiation exposure during the TMI accident produced the immune parameters which she observed. In fact, Dr. Tarasenko testified that it was not her purpose to interpret her findings. (Tr. at 588 ("[I]t was not my purpose to interpret these results. It was my purpose to obtain this data, to record these results.").) Moreover, her testimony confirms that at the point that she transmitted her findings to Professor Shevchenko, she did not have sufficient medical data to rule out other potential causes of the immunosuppression. (Tr. at 585.) Dr. Shevchenko, who has no experience or expertise in the area of immunology, read Dr. Tarasenko's report and reached the conclusion that the findings supported his hypothesis that residents of the TMI area were exposed to ionizing radiation during the TMI accident. (Tr. at 493; 2/21/95 Shevchenko Rpt. at 9.)

Plaintiffs argued during the in limine hearing that the dispute regarding the precise meaning of the Tarasenko study has arisen as a result of the court's ruling prohibiting Professor Shevchenko from testifying about the Tarasenko

immune study. (Tr. at 491-95.)[26] Plaintiffs contend that Dr. Tarasenko was part of a team of experts working under Professor Shevchenko, and that she can only testify to the component of the research which she performed. The court does not disagree with Plaintiffs' assertion. However, the court takes exception to Plaintiffs' argument that they have been placed in this "Catch-22" by the court. The court took no part in assembling Plaintiffs' team of experts or in preparing the reports of those experts. Dr. Shevchenko does not have the expertise to testify as to the mechanics of the immune study; this is why the court required Dr. Tarasenko to testify. It should not have come as a shock to Plaintiffs' counsel that the court would not allow Professor Shevchenko to opine as to the methodology of a scientific procedure performed by another scientist and about which Professor Shevchenko has little or no technical knowledge. Additionally, it should have been apparent to Plaintiffs that where the proffered testimony asserts that an immune study reveals that the TMI Plaintiffs suffer from

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26. Specifically, Plaintiffs' counsel argued as follows:

> Your Honor, that places the plaintiffs in a Catch 22. We have information in Professor Shevchenko's report that we're not allowed to use. We're supposed to bring the other witness here. We do that, and now we're not permitted to allow this witness to testify about it.
>
> If Professor Shevchenko could have testified about this in the first instance, we wouldn't be in this position. But based on that ruling, it's a can't-win situation for the plaintiffs the way the defendants are portraying it.

(Tr. at 494.)

immunosuppression brought about by their exposure to ionizing radiation during the TMI accident, Defendants' would be entitled to cross-examine on the methodology of that immune study. Plaintiffs' counsel placed themselves in the situation they are in long before this court made any rulings on the issue.

A different situation would exist if Dr. Tarasenko had issued a written report which reached the conclusion that the immune parameters observed in the TMI group resulted from exposure to ionizing radiation during the TMI accident. Were there such a report, the court would have no difficulty allowing Professor Shevchenko to testify that Dr. Tarasenko's study results corroborate his findings with respect to the tree study and cytogenetic analysis. No such report exists. Instead, Plaintiffs would have this court permit Professor Shevchenko to testify that after he filed his report with this court (which included the Tarasenko study), he had a discussion with Dr. Tarasenko at which time she confirmed that she had ruled out all other potential causative agents and determined that radiation was the cause of the immune parameters observed in the TMI samples.

The record somewhat contradicts the sequence of events advanced by Plaintiffs. Professor Shevchenko's written report, transmitted February 21, 1995, indicates that Dr. Tarasenko's study results support his findings with respect to radiation exposure. 2/21/95 Shevchenko Rpt. at 9. Dr. Tarasenko testified that "I had transmitted these results [of my analysis], and then I left Moscow." (Tr. at 588.) Dr. Tarasenko's report is dated February 15, 1995. She further testifies that she did not receive medical data until "after

I transmitted this text for translation." (Tr. at 589.) Thus, it seems that prior to Dr. Tarasenko receiving medical data on the TMI subjects, prior to her evaluation of that data and use of that data to rule out other potential causative agents, and prior to Professor Shevchenko's phone conversation with Dr. Tarasenko on this subject, Professor Shevchenko had already reached his conclusion that radiation caused the observed immune parameters. The court is left to question how Professor Shevchenko read a report that makes no mention of radiation as a possible causative agent, and based upon that report, concluded that the report supports a finding that the TMI group suffers from some variety of radiation induced immunosuppression. Moreover, Dr. Tarasenko's testimony indicates that Professor Shevchenko made this assessment without inquiring as to any other factors that might have caused the immunosuppression in the TMI group. (Tr. at 587 ("And Dr. Shevchenko did not at any later date request me to identify any possible underlying factors that might have resulted in the changes that we have observed.").) The evidence before the court demonstrates that Professor Shevchenko concluded that radiation was the causative agent without having knowledge of other potential causative agents, and that he may have offered this opinion before Dr. Tarasenko had the opportunity to review medical information relating to the study subjects. Professor Shevchenko will be precluded from testifying as to his use of the immune study as corroboration of the results he obtained in the tree study and cytogenetic analysis.

In accordance with § I of this memorandum, the court will consider the testimony of Dr. Tarasenko presented during the in limine hearings despite the fact that much of

her testimony went beyond the scope of her report. Defendants were permitted to cross-examine Dr. Tarasenko extensively on the testimony that the court will consider. On direct examination, Dr. Tarasenko testified to the inferences that she made based upon her study findings:

> The conclusion is this, characteristics that we have determined for inhabitants in the area of Three Mile Island, show almost . . . the same as characteristics found for the inhabitants of Muslomovo village and Urals.
>
> . . . . .
>
> In other words, our conclusion is this, changes that we see in inhabitants of the Three Mile Island region are even deeper than those who lived in that village and who were eradiated [sic] as a consequence of the Kyshtym accident.
>
> . . . . .
>
> Our conclusion is that the immunodepression was found in both these groups under comparison. TMI group and Muslumovo group, immunodepression was present. The extent of immunodepression, however, was more prominent in the Three Mile Island accident.

(Tr. at 513, 520.) On cross-examination, Dr. Tarasenko was asked to explain the methodology which she employed in

reaching these conclusions. The court will discuss that testimony in the context of its Rule 703 analysis.[27]

Rule 703 of the Federal Rule of Evidence provides that an expert may rely on any data that would reasonably be relied upon by other experts in the field. The Third Circuit has defined the district court's role in determining whether underlying data is of the type reasonably relied upon as follows:

> the judge must conduct an independent evaluation into reasonableness. The judge can of course take into account the particular expert's opinion that experts reasonably rely on that type of data, as well as the opinions of other experts as to its reliability, but the judge can also take into account other factors he or she deems relevant.

Paoli II, 35 F.3d at 748. In Paoli II the Third Circuit ruled on the district court's application of this rule in the context of a doctor's causation opinion linking exposure to PCBs with the plaintiffs' illnesses. The Third Circuit noted that "a physician who evaluates a patient in preparation for litigation should seek more than a patient's self-report of symptoms or illness and hence should either examine the patient or review the patient's medical records simply in order to determine that a patient is ill and what illness the patient has contracted." Id. at 762. The court concluded "we think that generally, a doctor only needs one reliable source of

27. The court will discuss Rule 703 prior to reaching the Daubert/Paoli II factors because the court finds the Rule 703 issue to be dispositive.

information showing that the plaintiff is ill and either a physical examination or medical records will suffice — but the doctor does need at least one of these sources." Id. (emphasis added). Upholding the district court's exclusion of testimony on the ground that the doctor had not based his opinion on reliable data, the Third Circuit provided the following basis for its holding:

> Dr. DiGregorio did not examine the plaintiffs or review their medical records; he simply relied on their answers to a questionnaire he gave them. Under the rule we have articulated above, Dr. DiGregorio could not even reliably conclude that the plaintiffs had any illness. In fact, Dr. DiGregorio admitted that without examining the plaintiffs he could not state to a reasonable degree of medical certainty that they had been injured as a result of exposure to PCBs. We now uphold the district court's decision to exclude his testimony as within the court's discretion. Dr. DiGregorio simply lacked the foundation to make the judgments he did. For that reason alone, the district court was correct to grant summary judgment. . . .

Id. at 763.

Although not identical, the situation presented by the Tarasenko proffer is analogous.[28] On cross-examination when

28. Where Dr. DiGregorio was a physician offering a causation opinion drawn from his evaluation of self-reported symptoms, Dr. (Cont'd)

asked whether the study subjects' pre-existing medical conditions could have caused the observed immune response, Dr. Tarasenko indicated that "after I examined these parameters of the immune system for the subject, I found that yes, indeed, some of their diseases could be responsible for some of the changes observed." (Tr. at 592.) Dr. Tarasenko's report echoes this concern:

> Such disturbances are observed in the patients who use immunodepressants (widely used antibiotics, aspirin and other medicines can be referred to this group of chemicals) and suffer from cancer, autoimmune diseases, syndrom [sic] of chronic weariness and others. It is undoubtedly necessary to carry out a dynamic examination of all persons in this group, regular observation of their immune status, medical and prophylactic measures.

2/15/95 Tarasenko Rpt. at 2 (emphasis added). During the in limine hearing, Dr. Tarasenko stated for the first time that she had made an attempt to rule out other causes of the observed immune responses. Dr. Tarasenko also stated that in ruling out other causes she relied solely upon the medical

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Tarasenko is a physician and immunologist offering a causation opinion based in part upon her reliance on self-reported medical histories. While the court finds the actual immune analysis conducted by Dr. Tarasenko to be scientifically valid and reliable, the court finds below that the inferences drawn from that study are not based upon "good grounds" because Dr. Tarasenko based her causal inferences upon her interpretation of unreliable medical data.

information provided to her by Dr. Snigiryova. (Tr. at 596.) According to Dr. Tarasenko, the medical summaries she received for each study subject included information regarding the "presence or absence of autoimmune diseases . . . [the] presence or absence of oncological cancer diseases, whether [the subject] . . . is a smoker or nonsmoker . . . [and] the extent of smoking, then patient's age, then a list of major diseases." (Tr. at 589-90.) Dr. Tarasenko did not review the medical records of nor personally examine her study subjects.

Presuming that Dr. Tarasenko did use the medical summaries provided by Dr. Snigiryova to rule out other potential causes for the immune responses, the court remains unconvinced that this data was reliable. The medical summaries are just that — summary medical history data. Although the summaries indicate that the subjects have been diagnosed as having certain major medical ailments, they provide no information as to a variety of less severe illnesses and treatments that could be responsible for the observed immune response (e.g. whether they take aspirin on a regular basis or whether they suffer from chronic stress or anxiety). Further, the court is troubled by Dr. Tarasenko's recent change of heart as to what steps should be taken before reaching a conclusion regarding the cause of the observed immune response. Her report indicates that she found it "necessary" to carry out a "dynamic" examination of all study subjects and to make a longer term observation of their immune responses. 2/15/95 Tarasenko Rpt. at 2. Yet at the in limine hearing, Dr. Tarasenko suddenly revealed that she could state "with a reasonable degree of medical certainty" that the immune responses were caused by exposure to large amounts of ionizing radiation based solely upon her

observation of cursory medical summaries. (Tr. at 512-13.) No explanation was given for this somewhat radical change in philosophy.

Based upon the record before it, the court will exclude the proffered immune study testimony of Dr. Tarasenko. The court finds that Dr. Tarasenko "lacked the foundation to make the judgments [s]he did." As such, her conclusions are not based upon "good grounds" and are not scientifically reliable. In accordance with this ruling, the court will likewise preclude Dr. Shevchenko from testifying that he relied upon the Tarasenko report to corroborate the findings of his tree study or cytogenetic analysis.

B. Dr. Bruce Molholt

Dr. Molholt's initial report filed with the court is dated April 8, 1993. In this report, Dr. Molholt opines that "the pattern of depressed lymphocyte production . . . may be used as a long-lived form of human dosimetry to back-calculate the intensity of population exposures during radiation exposures such as occurred during the TMI accident." 4/8/93 Molholt Rpt. at 1-2. Using this back-calculation methodology, Dr. Molholt reaches the conclusion that "[t]aken as a whole, the immunologic evidence supports the conclusion that human radiation exposures exceeded 100 rems as a result of the TMI accident." This report became the subject of Defendants' first motion in limine.

After briefing was complete, but before the court ruled on the motion, Plaintiffs submitted the 3/13/95 report of Dr. Molholt. According to Dr. Molholt, the purpose of this report

"is to examine the medical histories of each of the remaining 11 test plaintiff cases and determine, with reasonable scientific certainty, whether or not the cancers they each developed following . . . [the TMI accident] are more likely than not due to radiation exposures received as a result of the accident." 3/13/95 Molholt Rpt. at 3. An important part of Dr. Molholt's methodology in this report involved his use of "lymphocyte profiles" for the test Plaintiffs as a means of determining whether their neoplasms were induced by exposure to radiation. The court will provide a more thorough discussion of this methodology below.

On February 14, 1995, the court issued a preliminary ruling on Defendants' motion in limine to exclude Dr. Molholt's 4/8/93 report. The court found that the parties' briefs, read in conjunction with the record evidence, failed to provide sufficient information for the court to conduct an adequate Daubert/Paoli II analysis. In re TMI, Mem.Op. at 22 (M.D.Pa. February 14, 1995). The court took particular care within the body of its opinion to identify the areas where the court was having difficulty conducting its analysis and to describe the type of filing (e.g. briefing, references to scientific literature, submission of additional evidence) that would be most beneficial to the court in making the Daubert/Paoli II analysis.[29] On May 1, 1995, proportedly in response

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29. In its February 14 preliminary ruling on the in limine motion to exclude the 4/8/93 Molholt report, the court requested the following information: (1) evidence demonstrating that the lymphocyte back-calculation methodology is based upon a testable hypothesis or concise briefing of the issue; (2) evidence that Dr. Molholt's back-calculation methodology has been or is being subject

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to the court's February 14 order, Plaintiffs filed a third Molholt report. This report elaborates upon the March 13 report by, inter alia, providing supplemental lymphocyte and cancer incidence data.

During the first round of in limine hearings, Plaintiffs advised the court that they would withdraw a portion of the Molholt proffer. (11/17/95 Tr. at 681 ("The subject of the defendants' briefing on and attack on Dr. Molholt was his use of lymphocyte counts to back[-]calculate dose. . . . We were willing to have the motion granted in the limited aspect of the attack, which is the lymphocyte count, and not proffer Dr. Molholt to opine on that methodology.").) Plaintiffs further indicated that Dr. Molholt "would still be tendered consistent with the other aspects of his reports." (11/17/95 Tr. at 682.) Controversy has arisen as to what, if any, testimony Dr. Molholt can provide consistent with his other reports in light of the fact that the lymphocyte methodology has been withdrawn.

During the second round of hearings, the court held a lengthy conference with counsel in chambers on this issue

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to peer review; (3) briefing on the issue of whether the "reasonable expert" would rely solely upon flawed data in conducting a study; (4) provision by Plaintiffs of a concise response as to whether there were standards controlling the operation of Dr. Molholt's technique; (5) briefing on the issue of whether the back-calculation methodology is generally accepted; (6) a response to the question of whether Dr. Molholt's methodology bears any relationship to established and reliable methods; (7) evidence in support of the proposition that Dr. Molholt is qualified to testify in the areas of immunology and immunobiology; (8) evidence demonstrating that the Molholt methodology has any non-judicial use.

followed by an additional colloquy with Plaintiffs' counsel once court resumed. Plaintiffs argue that they withdrew only the methodology and conclusions associated with the use of lymphocytes to back-calculate dose. (Tr. at 650-51.) As such, Plaintiffs contend that the Molholt "corollary hypotheses" are still viable. When asked by the court during the in chambers conference to "[t]ell me now on the record" the exact purpose for which the lymphocyte testimony was withdrawn, Plaintiffs' counsel indicated that "our understanding was that it was withdrawn for the sole purpose of the attack made by the defendants that you could not back-calculate dose based upon lymphocyte counts." (Tr. at 658.) Defendants argue that the reports characterize the corollary hypotheses as "evidence for clinical lymphocyte depression and immunosuppression," and that this was precisely the line of testimony that they believed Plaintiffs withdrew. (Tr. at 648.)

Plaintiffs have placed two inconsistent arguments on the record with respect to the lymphocyte back-calculations and Dr. Molholt's May 1 report. The first sentence on the cover page of the May 1 report states that "[e]nclosed you will please find my response to the Court's memorandum of 14 February 1995 relating to Defendant's [sic] motion to exclude my testimony in limine in the ongoing TMI litigation." 5/1/95 Molholt Rpt. at 1. The only methodology at issue in the court's February 14 ruling was the lymphocyte back-calculation methodology. Accordingly, in the words of the report's author, the May 1 report was intended to respond to the court's 2/14/95 request for information supporting the lymphocyte back-calculation methodology. Since withdrawing the lymphocyte hypothesis, Plaintiffs

have argued that the corollary hypotheses set forth in the May 1 report stand as an independent methodology from which Dr. Molholt can infer exposure.[30] To the contrary, the Molholt report itself characterizes the corollary hypotheses as "relevant scientific data in support of the first [(Lymphocyte back-calculation)] hypothesis." 5/1/95 Molholt Rpt. at 3-4.[31]

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30. At the hearings, the court engaged in a rather lengthy colloquy with Plaintiffs' counsel on this issue. (Tr. at 669.) Plaintiffs' counsel argued that the withdrawal of Dr. Molholt's lymphocyte methodology was a "tactical decision," and that they "are not conceding anything wrong with the methodology." (Tr. at 666.) Counsel further stated that Plaintiffs "were withdrawing the offer of this expert on that basis for calculating dose." (Id.) Plaintiffs are clearly entitled to make such a tactical decision. They are not, however, entitled to bring a dose opinion in through the back door. The court repeatedly asked Plaintiffs' counsel to explain how Dr. Molholt could claim that decreased lymphocyte counts resulted from irradiation without testifying that a certain dose is medically necessary to decrease the lymphocytes in the first place. (Id. at 667-69.) The court's questions elicited the following responses: "Well, I'm not sure that he's saying — I mean, he is attributing all these elements as a whole that if you have all of these elements that —" (id. at 668); "I don't know that — I guess there has to be some dosage. Without some dosage, you would have — I'd have to agree with that. If it comes from the radiation, then there would have to be some dose of radiation to report." (Id. at 668-69.) Plaintiffs cannot have it both ways. Withdrawing Dr. Molholt's methodology whereby he uses lymphocyte data to back-calculate dose means that Dr. Molholt cannot use depressed lymphocyte counts as a basis for inferring any dose to the TMI population.

31. As an aside, the court notes that Dr. Molholt himself appears to believe that "Lymphocyte depression and

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The following observations can be made. Relying on the plain language of the May 1 report, the court finds that the report was filed in response to the court's request for further briefing on the lymphocyte back-calculation methodology. This methodology has been withdrawn by Plaintiffs. Such a withdrawal necessarily includes a withdrawal of reports submitted in support of this methodology. Relying, however, on Plaintiffs' most recent corollary hypothesis arguments, the court reaches a different yet troubling conclusion. To credit Plaintiffs' argument that the corollary hypotheses stated in the May 1 report represent an independent methodology through which Dr. Molholt can opine about exposure and causation, the court must first: 1) ignore the express language of the May 1 report and thus, the intention of its author, and 2) accept Plaintiffs' submission of a new expert report, filed without leave of court, subsequent to the filing deadlines, as an exhibit to an unrelated brief.

The court is neither comfortable with nor inclined to ignore the plain language of Dr. Molholt's report. Consequently, the court finds that the May 1 report was submitted in response to this court's request for further

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immunosuppression as biomonitors of radiation exposure have been withdrawn from my testimony with respect to the in limine hearings. . . ." (Pls.' Answer and Mem. of Law in Op. to Defs.' Motn. in Limine to Exclude the Testimony of Pls.' Experts on Medical Causation at Ex. B (1/31/96 Molholt Aff.).) The court has admitted this affidavit for the sole purpose of making this observation. It is excluded for all other purposes pursuant to § I of this memorandum of law.

briefing on the lymphocyte back-calculation methodology. Plaintiffs have since withdrawn that methodology. As such, the May 1 report is no longer relevant to this case. Based upon the foregoing, the court will exclude the May 1 report of Dr. Molholt. Remaining for the court's consideration is Dr. Molholt's March 13, 1995 report.

1. The Proffered Testimony

According to the introduction to the March 13 report, the "report focuses on three aspects of the histories of each test plaintiff" rather than upon "mechanisms of radiation carcinogenesis." 3/13/95 Molholt Rpt. at 3. These three "aspects" are as follows:

> 1. Were test plaintiffs exposed to sufficient ionizing radiation in 1979 to experience lymphocyte depression and/or immunosuppression? Blood analyses and decline in health status are indicators.
>
> 2. Were there other indications by Plaintiffs of acute radiation exposure at the time of the TMI-2 accident, such as erythema, nausea, iodine taste, etc.?
>
> 3. Were the test plaintiffs in areas of known radiation exposure at the time of the TMI-2 accident, i.e., downwind or in areas which have borne subsequent evidence of radiation exposure such as arboreal apical ablation?

Id. Based upon an evaluation of these factors, Dr. Molholt opines "with reasonable medical certainty" that "radionuclide releases from the TMI accident were causally related to the subsequently observed statistically significant increases in birth defects and cancers among exposed populations." Id. at 7. Additionally, Dr. Molholt states that it is the "thesis" of his report that "radiation doses were [greater than or equal to] 100 rems to the majority of test plaintiffs." Insofar as Dr. Molholt uses lymphocyte data to back-calculate dose, the methodology has been withdrawn by Plaintiffs and will not be considered by the court.[32] The court will now evaluate the balance of the March 13 report.

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32. As the preceding discussion indicates, Plaintiffs "were willing to have the motion [in limine] granted in the limited aspect of the attack, which is the lymphocyte count." (11/17/95 Tr. at 681.) Plaintiffs further indicated that Dr. Molholt "would still be proffered consistent with the other aspects of his report." (Id.) Contrary to Plaintiffs belief, they cannot withdraw the lymphocyte methodology as a "primary hypothesis" and yet rely upon the same methodology as a component of a broader analysis. If a methodology is withdrawn it is withdrawn as to all applications. The court can make no distinction between the way that Dr. Molholt used the lymphocyte data in his April 8, 1993 report and the way he uses the data in the present report, save that in the present report Dr. Molholt uses the lymphocyte data in conjunction with other data (nevertheless, the lymphocyte data is still used to infer a dose of greater than or equal to 100 rem). As such, the court finds it inconsistent to withdraw the methodology as it appeared in the April 8 report, and yet admit the same methodology as it appears in the March 13 report. Consequently, the court will exclude the portion of Dr. Molholt's March 13 report that includes use of lymphocyte data to infer dose as the methodology is identical to back-calculation methodology withdrawn by Plaintiffs.

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2. The Daubert/Paoli II Analysis

a. Is the Methodology Based Upon a Testable Hypothesis?

Dr. Molholt's hypothesis, that the majority of test Plaintiffs were exposed to greater than or equal to 100 rems of radiation and that increases in cancer and birth defects are causally related to radiation exposure from the TMI accident, is testable. This is not in dispute. The issue is whether Dr. Molholt tested his hypothesis. According to Dr. Molholt's report, he "attempted to apply four weighted scores to six relevant causal criteria." 3/13/95 Molholt Rpt. at 17. The record is not clear as to how Dr. Molholt scored each category. In his report, Dr. Molholt states that "[t]hese six contributors to causal certainty are not equally weighted." Id. (emphasis added). While testifying at the hearings, Dr. Molholt stated that he "attempted to weigh these six criteria equally." (Tr. at 841 (emphasis added).) When asked about this seeming contradiction Dr. Molholt testified as follows:

> although my objective was to weigh each of these equally, that is, to give them one-sixth of the total — actually 16.6 percent of the total score, in fact, when there was an outstanding criterion like dicentric chromosome formation, that tended to overwhelm the other five criteria, such that if I had been in a position of making the 50 percent reasonable scientific certainty standard employed or not, in other words, if I was at that boundary, I would have weighed the chromosomal criteria more than damaged trees or more than lymphocyte depression or more than lag time.

(Tr. at 842.) Defense counsel followed up by asking "if you got a positive answer on chromosome abnormalities, that carried the day?" (Id.) Dr. Molholt provided the following clarification:

> If I were at that boundary between certainty and uncertainty, which is the 50 percent standard that has been employed, at least up until Daubert and Paoli [II] . . . what I was attempting to do was to quantify these criteria in such a way that I could, on an individual basis of each one of these, make a 50 percent determination, but then collectively to say, on that system of three, two, one, you have six criteria, the highest score is 18 if all six criteria are satisfied in terms of what we know about exposure requirements and carcinogenesis, radiation carcinogenesis.
>
> So if those six criteria were all satisfied to the fullest, you would have a score of 18. That's the highest you could get. The lowest you could get is if none of them were satisfied at all, and that's zero. So I took nine as being the boundary.

(Tr. at 842-43.) When asked "if they hit nine, then you said that's enough?" (Tr. at 843) Dr. Molholt responded:

> No, I didn't. That's when I would reach into my basket of tricks and pull out dicentric chromosomes or some other characteristic that I thought deserved more credence than trying to equally weigh them.

> Now, as it turned out . . . I didn't have any that were nine.

(Id.) Based upon the foregoing, the court finds that Dr. Molholt did not test his hypothesis. His method of deriving weighted scores for his six factors is entirely subjective, and as such, it cannot be characterized as a scientific means of testing his hypothesis. This factor will weigh against the admission of the proffered testimony.

b. Has the Methodology Been Subject to Peer Review?

With respect to Dr. Molholt's causation and exposure opinion, Plaintiffs make no direct argument in support of this factor. Plaintiffs' legal argument focuses on its characterization of Dr. Molholt's methodology as a differential diagnosis. The court surmises that Plaintiffs would argue that the case law supports a finding that there is no way to "peer review" a differential diagnosis because such diagnoses are made by physicians on the basis of their own experience. Insofar as Dr. Molholt claims to have made a differential diagnosis, this argument would be accurate. The court notes, however, that in their brief in opposition to Defendants' motion in limine Plaintiffs state that "Dr. Molholt's techniques are simply extensions of the principles utilizes as a toxicologist and risk assessor applied to the unique circumstances of this case." (Pls.' Brief in Op. to Defs.' Motn. In Limine to Exclude Pls.' Medical Causation Experts at 51.) In that same brief, Plaintiffs also argue as follows:

> Dr. Molholt . . . . is not analyzing the information presented in his report as a medical doctor, a radiation biologist, a physicist, a nuclear engineer or a meteorologist. He is a toxicologist and carried out his analysis consistently with well-accepted principles of toxicology.
>
> . . . . . .
>
> Defendants' arguments that Dr. Molholt merely examined a checklist of factors and did not engage in a differential diagnosis akin to a medical doctor's examination, is wholly without merit. Dr. Molholt applied his expertise [in risk assessment] to assessing the toxicological significance of various cardinal signs of high radiation doses.

(Id. at 114 & 117.) Plaintiffs appear to argue that Dr. Molholt has performed both a differential diagnosis and a risk assessment. This characterization serves them well as they argue for application of the more liberal standard of admissibility germane to differential diagnoses, while at the same time arguing that Dr. Molholt has used his expertise as a risk assessor to determine the "toxicological significance" of his findings. The evidence before the court indicates that a toxicological risk assessment is a scientific methodology akin but not identical to a differential diagnosis. This distinction will be discussed at greater length below. The court finds that based upon the record evidence, Dr. Molholt's study is best characterized as a toxicological risk assessment. As such, the peer review factor is relevant. There is no record evidence demonstrating that the particular

methodology of weighting scores for different criteria has been peer reviewed. Accordingly, this factor will weigh against the admission of the proffered testimony.

c. Is There a Known or Potential Rate of Error?

The court has already found Dr. Molholt's weighting scheme to be highly subjective and therefore unscientific. As such, the court finds the potential rate of error of Dr. Molholt's methodology to be high. This factor weighs against the admission of the proffered testimony.

d. Were There Standards Controlling the Technique's Operation?

The court finds that this factor is not directly relevant to Dr. Molholt's study insofar as he did not perform any laboratory techniques that would necessitate the imposition of certain standards. To the extent that Dr. Molholt's methodology was subjective rather than objective, an important scientific standard was effectively absent from the technique. Nevertheless, because the court finds this standard not to be directly relevant, it will weigh neither in favor nor against the admission of the proffered testimony.

e. Is the Methodology Generally Accepted?

Plaintiffs argue that "[r]egarding general acceptance, Dr. Molholt relies upon a wide range of evidence that toxicologists customarily rely upon in analyzing the effects of exposure. That is demonstrated here by the numerous citations to the Reference Manual." (Pls.' Findings at 116.)

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The Reference Manual on Scientific Evidence provides the following discussion regarding toxicologic testimony supporting the finding of a causal relationship between an individual's exposure and the onset of disease:

> An expert who opines that exposure to a compound caused a person's disease engages in deductive clinical reasoning. In most instances, cancers and other diseases do not wear labels documenting their causation. The opinion is based on an assessment of the individual's exposure, including the amount, the temporal relationship between the exposure and disease, and exposure to other disease-causing factors. This information is then compared to research data on the relationship between exposure and disease. The certainty of the expert's opinion depends upon the strength of the research data demonstrating a relationship between exposure and the disease at the dose in question and the absence of other disease causing factors.

Ref.Man. at 205 (emphasis added). The court finds Dr. Molholt's methodology to differ from the generally accepted methodology defined in the Reference Manual. Dr. Molholt's assessment of exposure in his report was based upon his lymphocyte back-calculation methodology and other "[a]ncillary evidence." 3/13/95 Molholt Rpt. at 6. In the report Dr. Molholt notes that:

> Ancillary evidence for radionuclide exposures during this period include:

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> Frequenting an area known to be downwind during radionuclide releases, especially during the period 28-30 March 1979. In many cases proximity to TMI is important in that plumes tend to disperse with distance. However, in the first few days of the accident, it appears that plumes may have traveled for miles in virtually every direction with little dispersion (Vergeiner, 1995).
>
> Indications of radiation exposure at the time of the accident including erythema, metallic taste, eye or mucous membrane irritation and nausea either by test plaintiffs or members of their immediate family.
>
> Local indications of radiation exposure as preserved in the botanical record. In particular, as detailed by plaintiffs' experts Drs. Gunckel and Shevchenko, trees provided sensitive and long-lasting monitors of acute radionuclide releases in areas surrounding Three Mile Island during the 1979 reactor accident (Shevchenko, 1994; Gunckel, 1994).

3/13/95 Molholt Rpt. at 6-7. Based upon his evaluation of lymphocyte data and the ancillary evidence, Dr. Molholt concludes that "[a]s a direct consequence of the accident, individual off-site exposures exceeded 100 rems for many persons, which conclusion also exceeds official estimates of dose by over three orders of magnitude." Id. at 7.

The Reference Manual notes that "[e]vidence of exposure is essential in determining the effects of harmful

substances." Ref.Man. at 206. Three approaches are defined for measuring potential exposure: 1) "where direct measurements cannot be made, exposure can be measured by mathematical modeling"; 2) "using direct measurements of the medium in question"; and 3) "directly measur[ing] human receptors through some form of biological monitoring." Id. "Ideally, both environmental testing and biological monitoring are performed; however, this is not always possible." Id.

The court finds that the methodology used by Dr. Molholt to render a causal opinion in this case is not generally accepted. The accepted toxicological methodology would first ascertain exposure and dose, and then utilize deductive clinical reasoning to make the causal link between exposure and subsequent illness. Dr. Molholt has blurred the distinction between these steps. He uses substantially the same information[33] to back-calculate dose that he uses to support his finding of a causal link. Moreover, Dr. Molholt makes specific findings that the test plaintiffs' neoplasms are causally related to exposure during the TMI accident without quantifying a dose for any of the Plaintiffs. Because the evidence presented in support of Dr. Molholt's report fails to demonstrate that his report is based upon reliable evidence of exposure, the court finds that Dr. Molholt's methodology is not generally accepted.

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33. The court notes that the plume dispersion data relied upon by Dr. Molholt has been found by this court to be scientifically unreliable; the evidence of acute radiation exposure (erythema, metallic taste, nausea, etc.) is based not upon medical records but upon responses to questionnaires circulated by Plaintiffs' consultants following the accident; and, the lymphocyte back-calculation methodology has been withdrawn by Plaintiffs.

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f. Is There a Relationship Between the Technique and Methods that are Established to Be Reliable?

The court finds that Dr. Molholt's technique bears little relationship to the established and reliable methods for assessing whether a causal link exists between exposure to a toxic substance and the subsequent onset of illness. During the in limine hearing, Dr. Molholt testified as to how a risk assessment typically proceeds. First, one defines the source term. (Tr. at 932-33.) Next, one examines the pathways of releases, quantifies the releases, and examines the transport mechanisms by which those releases reach the individual in question. (Tr. at 933-34.) One then calculates the dose at the point of interest, given the individual's type of cancer. (Tr. at 934.) Finally, one refers to epidemiological data if there is any, and there is a "plethora" of such data for the carcinogenic effect of radiation, to quantify the probability that the individual's cancer was caused by the calculated organ dose received. (Tr. at 934-35.) The record does not support the assertion that Dr. Molholt followed this methodology in the context of the 3/13/95 report. A source term was not defined,[34] and there was no calculation of dose

34. To the extent that Dr. Molholt may have relied on Dr. Webb's source term, that calculation as been disavowed by Dr. Webb himself. The only references to dose literature that the court finds within the report are listed in Dr. Molholt's table of references. They are "Takeshi, S. (1979) NRC's gross underestimation of the radioactive releases and population doses during the TMI-2 accident. Nucl Eng, vol. 26, no. 3" and "Shevchenko, V.A. (1994) Concerning the dose to any individual from the TMI Unit 2 accident. Affidavit submitted 6 July 1994 (15 pp.)." The court notes that it has found Professor Shevchenko's quantified dose estimates to be scientifically unreliable.

at the point of interest (organ dose). Dr. Molholt's technique bears little resemblance to his own articulation of established and reliable methods.

Based upon the foregoing, the court finds that this factor weighs against the admission of the proffered testimony.

g. What are the Qualifications of the Expert Based Upon the Methodology?

Defendants argue that while Dr. Molholt "may be qualified to perform risk assessments in fields other than radiation, he does not appear to be qualified to address the specific toxin involved in these cases." (Defs.' Findings at 62.) The court cannot agree with Defendants. Pursuant to Paoli II the court must apply this factor liberally. The court finds Dr. Molholt to be qualified to perform a toxicological risk assessment. As such, the court finds him qualified to testify based upon the methodology at issue. This factor will weigh in favor of the proffered testimony.

h. Does the Methodology Have Non-Judicial Uses?

Plaintiffs argue that the non-judicial applications of Dr. Molholt's methodology "include risk assessment at hundreds of superfund cites [sic], risk assessment with respect to workplace exposures to substances, and more." (Pls.' Findings at 117.) The court agrees with Plaintiffs that, as a general matter, toxicological risk assessments have far reaching non-judicial uses. The issue, however, is whether the methodology employed by Dr. Molholt in his March 13

report has any non-judicial use.[35] There is no evidence before the court to indicate that it does. Accordingly, this factor weighs against the admission of the proffered testimony.

3. Conclusion

The court's Daubert/Paoli II analysis weighs heavily in favor of excluding the proffered testimony as scientifically unreliable. In addition to the factors discussed above, the court finds additional support for finding Dr. Molholt's methodology scientifically unreliable in his inability to consistently articulate the same methodology. The court recognizes that on one level contradictions in Dr. Molholt's report and subsequent deposition and hearing testimony are issues of credibility that are not presently before the court. On a second level, however, the court finds these contradictions to be directly relevant to the reliability of the proffered testimony. If an expert's answer to a question regarding his methodology changes each time he is posed with that same question, it follows that the methodology is unreliable insofar as the expert himself is unable to state with certainty what steps or factors comprise his methodology.

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35. Dr. Molholt himself distinguished the risk assessment he performed for this case from a traditional risk assessment:

> In that we have a different set of parameters that are available for test plaintiffs than those accorded in a traditional risk assessment, the approach had to be modified in order to use the data at hand.

(Tr. at 935-36.)

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The court finds the following examples to be illustrative of its point. At the hearing Dr. Molholt testified that the reason he only presented plots of lymphocyte counts for five of the eight test Plaintiffs was that he found the five cases to be "illustrative." (Tr. at 1246.) At his deposition, Dr. Molholt testified that "the honest answer is when I first started plotting these data that's all the room I had on my graph paper." 6/1/95 Molholt Dep. at 174. Dr. Molholt testified that at the time he issued his 3/13/95 report, he had not done specific organ dose calculations. (Tr. at 778.) Yet he also testified that "[m]y assessment was that 99 percent of the organ specific dose came from uptake of the radionuclides rather than from cloud shine or an external source." (Tr. at 781) This raises the obvious question of how a methodology that did not include calculation of a specific organ dose could allow one to assess that 99 percent of the organ dose came from the uptake of radionuclides? At his deposition, Dr. Molholt testified that to determine whether a test plaintiff was in the pathway of the plume during the accident "I used Ignaz Vergeiner's vectors and meteorological dispersion models." 6/1/95 Molholt Dep. at 27. At the hearing, Dr. Molholt testified that "I believe that when I did the initial analysis . . . my initial data came from Jan Beyea. . . . In the middle of the analysis . . . I saw for the first time Vergeiner's approach to describing plume distribution. I then attempted to apply his data. . . . I did defer to Vergeiner's data when there was an inconsistency between the two. . . ." (Tr. at 943-44.) At his January 1995 deposition, Dr. Molholt testified that nausea, as an acute effect of radiation, was associated with a dose of 300 rems. (1/26/95 Molholt Dep. at 255.) During his June 1995 deposition, Dr. Molholt testified that nausea was associated with a dose of 50 to 100 rems. (6/1/95 Molholt

Dep. at 39-40.) At the hearings, Dr. Molholt testified that nausea was associated with a dose of 150 rems. (Tr. at 845.) Finally, during his June 1995 deposition, Dr. Molholt testified that he did not consider or make an adjustment as to whether a test plaintiff's cancer was unusual for someone of their age. (6/1/95 Molholt Dep. at 67.) At the hearings, Dr. Molholt testified that he made this consideration in conjunction with his "age at diagnosis" factor. (Tr. at 854.)

Based upon the foregoing, the court finds the proffered testimony of Dr. Molholt to be scientifically unreliable and therefore inadmissible. As an additional basis for exclusion, the court finds that Dr. Molholt failed to rely upon the type of data that the reasonable expert in the field, performing a toxicological risk assessment on the test Plaintiffs, would have relied upon. Fed.R.Evid. 703; see supra at 84-85.

C. Dr. Luis F. Fajardo

Dr. Fajardo is a well respected physician who is board certified in pathology. He is presently a Professor of Pathology at the Stanford University School of Medicine, and has research and teaching experience in the area of radiation injury. On July 29, 1994, Plaintiffs filed Dr. Fajardo's one-page report. In that report, Dr. Fajardo indicates that he has reviewed the "clinical records and other documents" of eight current and one former test Plaintiff.[36] Based upon his review of the records, Dr. Fajardo concluded that Plaintiffs did exhibit the stated neoplasms and that such

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36. Plaintiff Cecilia Macri, whose records Dr. Fajardo examined, has been stricken as a test Plaintiff.

neoplasms "can be induced by ionizing radiation." 7/29/94 Fajardo Rpt. Dr. Fajardo also reached the following conditional finding:

> Provided that a significant release of radionuclides did occur in the accident (resulting in acute exposures equal to, or greater than, 10 cGy per person), and that an increase in the incidence of cancers in the presumably affected population can be demonstrated after the accident, it is more likely than not that in the above cases, the stated neoplasms were causally related to radiation from the Three Mile Island accident.

7/29/94 Fajardo Rpt. The report contained neither a statement of his methodology nor reference to materials he relied upon beyond the test Plaintiffs' clinical records. On its face, this filing is in violation of Rule 26(a)(2)(B) of the Federal Rules of Civil Procedure.

On January 30, 1996, eleven months after the expert report filing deadline and without leave of court, Plaintiffs filed the "supplemental affidavit" of Dr. Fajardo.[37] In its

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37. Dr. Fajardo characterizes his supplemental affidavit as "an explanation of my opinion rendered on July 29, 1994." 1/30/96 Fajardo Rpt. at 1. At the outset, the court will note that parts of the supplemental affidavit read more like a piece of persuasive legal writing than a medical report. See, e.g., 1/30/96 Fajardo Aff. at 1 ("My conclusion that these persons developed these neoplasms is based on my examination of clinical records, and pathology reports in particular. As far as I know this aspect of the litigation is

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January 5 ruling, this court explained the rationale for its November 9, 1995 order excluding certain of Plaintiffs' other untimely filed reports during the first round of hearings. "[F]or the purposes of this litigation, the discrete body of factual evidence with respect to the issue of dose [and medical causation] became fixed on March 1. . . . attempts to build on this body of facts after the filing deadline passed were misplaced." In re TMI, 911 F.Supp. at 829. Thus, with respect to Dr. Fajardo's reports, Plaintiffs violated Rule 26 with the filing of the initial report, and violated at least three separate orders of this court with the filing of the supplemental affidavit (11/3/94 Scheduling Order; 11/9/95 order; 1/5/96 order). To date Plaintiffs have offered no explanation or justification on the record for the late filing of the supplemental Fajardo affidavit.[38] Pursuant to the

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unquestionable.") (emphasis added); id. at 2 ("I am aware that Drs. Gunckel and Crawford-Brown are being prevented from testifying and that the plaintiffs have asked the Court to reconsider this decision. The Court's determination does not undermine the foundation for my opinion that exposures did exceed 10 rem."); id. ("In contrast to the above, the defendants claim that the exposures were in the order of millirems. . . . The discrepancy between the exposures claimed by the plaintiffs and those admitted by the defendants can be explained by the location of the dosimeters (TLD) on which the defendants base their data. There were several gaps in the placement of the TLD, most prominently between approximately 2.7 miles and 9 miles from the TMI reactor.").

38. Surprisingly, Plaintiffs make no mention of the timeliness issue in their findings of fact and conclusions of law. This is notable insofar as the majority of Dr. Fajardo's hearing testimony was subject to Defendants' continuing objection as to the untimely filed supplemental affidavit.

court's discussion in § I of this memorandum of law, the court will exclude Dr. Fajardo's January 30 supplemental affidavit. As such, the court will sustain Defendants' continuing objection to that portion of Dr. Fajardo's in limine testimony which goes beyond the scope of his timely filed report and deposition testimony.[39]

Due to the brevity of Dr. Fajardo's timely filed report, the court's Daubert/Paoli II analysis will necessarily be brief.

1. Is the Methodology Based Upon a Testable Hypothesis?

Based upon his timely filed report, the court finds that Dr. Fajardo's hypothesis is that presuming exposure to radiation greater than or equal to 10cGy during the TMI accident, the test Plaintiffs' neoplasms were induced by the radiation exposure. Insofar as the etiology of each test Plaintiffs' neoplasm can be identified with any degree of certainty, Dr. Fajardo's methodology is testable. With respect to the etiology of radiation-induced cancers, the Bier V report notes that a description of the risk of cancer from exposure to ionizing radiation "is bound to be inexact since the etiology of radiation-induced cancer is complex and incompletely understood." National Research Council, Bier V Rpt. 161 (1990). Despite the limitations based upon incomplete scientific knowledge that do exist, the court finds that Dr.

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39. The court will admit deposition testimony that goes beyond the scope of the timely filed report as Dr. Fajardo's deposition was taken in June of 1995. Defendants have had ample opportunity to review the deposition testimony and were permitted to further question Dr. Fajardo as to that testimony at the in limine hearing.

Fajardo's hypothesis can be tested by ruling out other potential etiologies.[40] Dr. Fajardos' timely filed report does not offer any discussion of whether Dr. Fajardo made any attempt to rule out other potential etiologies. Dr. Fajardo's deposition testimony supports the contention that he made some attempts to rule out other causes. (See, e.g., 6/7/95 Fajardo Dep. at 42 (indicating that he confirmed each test Plaintiffs' cancer diagnosis and "determined that there wasn't anything [in their medical histories] that would cloud the possibility" of the neoplasms being radiation-induced); id. at 43 (indicating that he "was satisfied that in these cases . . . there were no pre-existing conditions that would indicate that these individuals had acquired such cancers prior to the exposure to radiation"); id. at 45-49 (explaining conditions he evaluated and literature he relied upon to determine whether the neoplasms were radiation-induced).)

The court finds that Dr. Fajardo made some attempt to test his hypothesis. To the extent that Defendants argue that Dr. Fajardo's testing of the hypothesis could have been more rigorous, such an argument goes more to weight than admissibility. This factor will weigh in favor of the admission of the proffered testimony.

2. Has the Methodology Been Subject to Peer Review?

The court can find nothing in Dr. Fajardo's report, deposition testimony or hearing testimony to suggest that

40. The court cannot require Dr. Fajardo to identify the etiology with complete certainty where no scientist in the relevant field could make such a determination.

the methodology he employed to determine the etiology of the test Plaintiffs' neoplasms has been subject to peer review. In their findings of fact, Plaintiffs note that "Dr. Fajardo has been accepted in previous litigation as an expert witness on the question of whether radiation exposure caused radiation injury. In those instances, he used the same methodology for determining causation as he used for determining causation in the instant litigation." (Pls.' Findings at 108.) During Dr. Fajardo's June 7, 1995 deposition Defendants' sought information as to the specifics of other cases in which Dr. Fajardo has been involved. (Fajardo Dep. at 8 ("I would ask that [Plaintiffs' counsel] . . . provide us with a list of the names of the cases in which he's provided testimony.").[41]

On cross-examination at the in limine hearing Defendants again attempted to elicit precise information regarding Dr. Fajardo's work in connection with other lawsuits. (Tr. at 1039.) Dr. Fajardo had difficulty recalling specific information about his prior participation in other cases. (Id.) In their findings of fact, Defendants aver that "[t]he list requested at the deposition has never been provided to defendants' counsel." (Defs.' Findings at 103.) It has been over one year since the filing of Dr. Fajardo's report and nine months since Dr. Fajardo's deposition. Plaintiffs have had ample time to provide Defendants with information regarding the other litigation that Dr. Fajardo has participated in as an expert. Because Plaintiffs have failed to produce this information, they will be prohibited from relying on Dr.

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41. Rule 26(a)(2)(B) of the Federal Rules of Civil Procedure requires a proffered expert to disclose "a listing of any other cases in which the witness has testified as an expert at trial or deposition within the preceding four years" within the expert's report.

Fajardo's experience in other litigation to argue that Dr. Fajardo's methodology has effectively been subject to peer review. Fed.R.Civ.P. 37(c). As there is no record evidence in support of this factor, it weighs against the admission of the proffered testimony.

3. Is There a Known or Potential Rate of Error?

Plaintiffs do not directly address the rate of error issue in their findings of fact and conclusions of law. No rate of error was identified by Dr. Fajardo in his reports, his deposition testimony or his hearing testimony. Defendants argue that Dr. Fajardo's methodology is "prone to huge error." (Defs.' Findings at 101.) Elaborating upon this statement, Defendants note that "Fajardo intellectually recognizes that different organs and tissues have different radiation sensitivities; by employing a method that ignores those distinctions, Fajardo introduces enormous error into his method." (Id.) In the sense that Dr. Fajardo is a medical professional giving an opinion based upon his review of relevant clinical records, the court finds the potential rate of error in Dr. Fajardo's "diagnosis" to be negligible. However, aspects of Dr. Fajardo's opinions cross over into the realm of risk assessment insofar as Dr. Fajardo attempts to state with scientific certainty that the test Plaintiffs' neoplasms are the result of exposure to ionizing radiation during the TMI accident. The court finds that in this context the potential rate of error associated with Dr. Fajardo's methodology increases. Dr. Fajardo did not calculate organ dose, evaluate dose-response curves for particular neoplasms, or make reference to the NIH radioepidemiologic tables. A formal risk assessment would have made use of this information.

The court finds the potential rate of error associated with Dr. Fajardo's methodology to be moderately high, although the court has had some difficulty quantifying this factor. Accordingly, this factor will weigh neither in favor nor against the admission of the proffered testimony.

4. Were There Standards Controlling the Technique's Operation?

Defendants argue that Dr. Fajardo discarded many standards that should have been used to control the operation of his technique. Specifically, Defendants contend that Dr. Fajardo:

> did not make latency periods part of the methodology reported in his timely submission, and when he recognized the issue in his untimely submission, he misused the minimum latency periods[;]
>
> . . . . .
>
> does not recognize the distinctive does response curves for different types of cancer[;]
>
> . . . . .
>
> does not calculate organ dose levels[;]
>
> . . . . .

> has no methodological step that accounts for the possibility that an unknown etiology caused the plaintiffs' neoplasms[;]
>
> . . . . .
>
> does not account for many risk factors that were relevant to individual test case plaintiffs.

(Defs.' Findings at 102.) The court agrees with Defendants that Dr. Fajardo's timely filed report provides little explanation of any standards that Dr. Fajardo might have employed. Dr. Fajardo's deposition testimony provides some clarification of this issue. With respect to taking potential risk factors into account, Dr. Fajardo testified that he "did take other factors into account." (6/7/95 Fajardo Dep. at 129.) He qualified this assertion by noting he did not "know if [he] . . . took into account every one of the many, many factors that have been considered by everybody . . . [b]ut the main factors that may influence cancer risk were taken into account." (Id.) Dr. Fajardo also indicated during his deposition that he did consider relevant latency periods in reaching his final opinion. (Id. at 89.)

The court finds that there is evidence on the record which demonstrates that there were some standards controlling the operation of Dr. Fajardo's technique. Moreover, the court finds that the two standards employed by Dr. Fajardo were particularly important standards. Defendants take exception with Dr. Fajardo's liberal application of the latency period factor insofar as Dr. Fajardo believes that on an individual basis latency periods may stray quite significantly from the

standard periods set forth in the literature. The court finds this argument to go to the weight of the testimony rather than its admissibility. Because the record reflects that Dr. Fajardo did employ some of the more important standards to control his technique, this factor will weigh in favor of the admission of the proffered testimony.

5. Is the Methodology Generally Accepted?

The court finds the answer to this question to depend upon how one characterizes Dr. Fajardo's proffered testimony. If Dr. Fajardo's methodology is characterized as a differential diagnosis, the court finds the method to be generally accepted. Paoli II, 35 F.3d at 758. The Third Circuit has found that "although differential diagnosis is a generally accepted technique, no particular combination of techniques chosen by a doctor to assess an individual patient is likely to have been generally accepted." Id. Thus, this court's inquiry must be flexible. Id. "However, to the extent that a doctor utilizes standard diagnostic techniques in gathering this information, the more likely [the court will be] . . . to find that the doctor's methodology is reliable." Id. The court finds Dr. Fajardo's review of clinical records, ruling out of other potential etiologies, and consideration of relevant latency periods to reflect a generally accepted form of the differential diagnosis technique. Further, the court finds that based upon these considerations, it would be generally accepted for Dr. Fajardo to reach a conclusion that it is more likely than not that the test Plaintiffs' neoplasms resulted from exposure to ionizing radiation.

If Dr. Fajardo's methodology is characterized as being more akin to a traditional risk assessment, the court is

inclined to find that his methodology is not generally accepted. The technical report of the International Chernobyl Project makes the following observations in describing its rationale in studying malignant neoplasms in the Chernobyl population following the accident:

> In order to determine whether radiation has caused certain health effects it is necessary to compare age and sex matched exposed and non-exposed populations. If there is a statistically significant excess of a health effect in the exposed population, then there is a given probability that the effect is due to radiation.
>
> . . . . .
>
> There are many confounding difficulties that arise in radiation carcinogenesis studies. The increased risk of radiation induced neoplasms following radiation exposure is expressed over many decades. During this time, there are likely to be changes in the age structure of the population, changes in exposure to other carcinogens as well as advances in detection and treatment of tumors.

International Chernobyl Project at Part F, pp. 382-83. In his hearing testimony, Dr. Fajardo seemed to contend that because he was making a causation determination for an individual rather than an entire population, a somewhat different methodology would apply. (Tr. at 1058.) When asked whether he quantified "the risk that [the test Plaintiffs] . . . might have gotten cancer without the radiation exposure,"

Dr. Fajardo responded that "in order to do that, you have to deal with populations rather than individuals." (Tr. at 1057-58.) After being asked a second time whether he quantified any comparison of risks, Dr. Fajardo testified "I couldn't. I don't think what you are proposing is possible, especially for individuals." (Tr. at 1058.)

The court is left to determine whether it is generally accepted for a medical doctor, based upon his examination of clinical records, his ruling out of some other potential causes and his consideration of the relevant latency periods, to determine that a given neoplasm's etiology is exposure to ionizing radiation in an amount greater than 10 cGy. To answer this question, the court refers to NCRP Statement No. 7, issued September 30, 1992, entitled "The Probability that a Particular Malignancy May Have Been Caused by a Specified Irradiation." According to the NCRP:

> Ionizing radiation is not generally known to leave a characteristic marker in those cells that are malignantly transformed and ultimately destined to become an overt malignancy. Thus, the most comprehensive medical examination, and accompanying laboratory tests done on a patient with a malignancy, however valuable they may be in determining the type and extent of the malignancy as well as its optimal treatment and prognosis, rarely provide definite information as to causation. As a result, it is not possible, on the basis of medical evaluation, to unequivocally prove or disprove a claim that a specific malignancy was caused by a specified radiation

> exposure. Therefore, another basis for judgment as to causation of the malignancy must be sought, despite the fact that new developments in molecular biology may ultimately link specific cancers with specific radiation exposures.

NRCP Stmt. No. 7 at 1.[42] The court finds that insofar as Dr. Fajardo claims that he can with medical certainty identify the etiology of a specific neoplasm as exposure to ionizing radiation based upon a medical evaluation, his methodology is not generally accepted. 1/30/96 Fajardo Aff. To this extent, the factor weighs against the admission of the proffered testimony. Because the court finds that Dr. Fajardo does not claim to have made an unequivocal determination, his methodology appears to be a hybrid of accepted and unaccepted methodologies. As such, this factor will weigh neither in favor nor against the admission of the proffered testimony.

6. Is There a Relationship Between The Technique and Methods That are Established to be Reliable?

As reflected in the court's discussion of the previous Paoli II factor, whether Dr. Fajardo's technique resembles accepted methods depends upon how his technique is characterized. As a differential diagnosis, the technique

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42. Reports of the NCRP have been recognized as authoritative by courts insofar as the NCRP is "composed of many of the most eminent scientists in this field in the United States." Johnston v. United States, 597 F.Supp. 374, 391 (D.Kan.1984). This court, likewise, finds the instant NCRP report to be authoritative.

resembles accepted techniques; as causal analysis, it does not. Because the method bears some resemblance to accepted methods, the court will weigh this factor in favor of the admission of the proffered testimony.

7. What are the Qualifications of the Expert Based upon the Methodology?

The parties and the court agree that Dr. Fajardo is a highly respected and eminently qualified radiation pathologist. Accordingly, this factor weighs in favor of the admission of the proffered testimony.

8. Are there Non-Judicial Uses of the Methodology?

Plaintiffs contend that "Dr. Fajardo performs differential diagnoses in his everyday practice of medicine" (Pls.' Findings at 116.) The record evidence indicates that although Dr. Fajardo does regularly perform differential diagnoses, this is the first time that he has used a differential diagnosis to find a causal link between alleged exposure to radiation and the subsequent development of certain neoplasms. Thus, the court cannot find that Dr. Fajardo uses the precise methodology employed in this case on a regular basis. This factor will weigh against the admission of the proffered testimony.

9. Conclusion

The Daubert/Paoli II analysis weighs in favor of the admission of the proffered testimony. Further, the court notes that in Paoli II the Third Circuit characterized the testimony

of two physicians who opined as to the causal link between certain health effects and exposure to PCBs as a differential diagnosis. Paoli II, 35 F.3d at 752-60. Accordingly, this court finds that it is not inappropriate to characterize Dr. Fajardo's opinion as a differential diagnosis. The court has some concern that scientifically, the causal link between PCBs and future health effects may be more readily apparent than the link between radiation exposure and the development of certain neoplasms. Insofar as this is true, it would seem less appropriate to rely solely upon a differential diagnosis to make the causal link between radiation and a subsequent neoplasm. Having no knowledge of the science relating to PCBs as carcinogens or promoters of other negative health effects, the court is not in a position to distinguish Paoli II.

Based upon the foregoing, the court finds that its Rule 702 analysis weighs in favor of admitting Dr. Fajardo's proffered differential diagnosis testimony. The court feels constrained by the legal precedent to find that the issue of whether it was appropriate to use a differential diagnosis in this context goes to weight rather than to admissibility.

10. Rule 702 "Fit" and Rule 403

Defendants argue that the proffered testimony does not have the requisite "fit" with the instant litigation for two reasons. First, Defendants contend that if Dr. Fajardo's methodology were found to be reliable, "it would depend upon proof of dose to the organ or tissue of interest, not just evidence of dose to the entire population." (Defs.' Findings at 97.) Because, Defendants claim, Plaintiffs have no evidence regarding organ doses to each test Plaintiff, Dr. Fajardo's methodology cannot be applied to this case. The

court has found Dr. Fajardo's proffered testimony to be scientifically reliable pursuant to Daubert and Paoli II despite the lack of organ dose information. As such, the court finds Defendants' first argument to be moot.

Second, Defendants argue that "[Dr.] Fajardo's 10 rem level is a vehicle for ruling out the possibility of radiation causation, but is, by his own acknowledgment, useless for ruling causation in for the specific cancers at issue." (Defs.' Findings at 97.) Even if Defendants' statement is true, the court finds that it is not relevant to the fit issue. Whether all of Plaintiffs' evidence supports a finding of specific causation for each of the test Plaintiffs is a question to be answered at the summary judgment stage or the conclusion of trial. At this stage, the court finds the testimony to "fit" because it will assist the jury in reaching the ultimate issue of whether Plaintiffs suffered damages as a result of exposure to ionizing radiation during the TMI accident. The court can find no legal support for the proposition that each causation expert must opine as to both general and specific causation. Further, the purpose of the in limine process is not to determine whether Plaintiffs have met their burden for producing sufficient evidence to support the causation aspect of their case. Accordingly, the court finds Defendants' second argument to be misplaced at this stage in the proceedings.

Finally, the court notes that it finds that the proffered testimony is not exceptionally confusing and thus does not warrant exclusion pursuant to Rule 403 of the Federal Rules of Evidence. Based upon the foregoing, the court will admit the proffered testimony of Dr. Fajardo. At trial, Dr. Fajardo will be confined in his testimony to matters covered in his timely filed report and his deposition. The court stresses that

it will not liberally construe this ruling — anything not specifically addressed in the timely report or deposition is inadmissible.

V. Conclusion

In accordance with the foregoing discussions, the court will exclude certain of Plaintiffs' untimely filed expert reports; grant in part and deny in part Defendants' motion for reconsideration of the court's January 5, 1996 memorandum and order as it pertains to Professor Shevchenko; deny in part Defendants' motion in limine to exclude the Wing cancer incidence study; and grant in part and deny in part Defendants' motion in limine to exclude Plaintiffs' experts on medical causation. The court will issue the balance of its in limine opinion, pertaining to Thomas Winters, Sigmund Zakrzewski, Theodore Sterling and David Lochbaum on or before April 5, 1996. An appropriate order will be issued.

ORDER

In accordance with the accompanying memorandum of law, IT IS HEREBY ORDERED THAT:

1) All supplemental affidavits filed after January 5, 1996, are excluded;

2) Supplemental affidavits filed subsequent to the March 1, 1995 filing deadline and prior to January 5, 1996, are admitted to the extent stated in the accompanying memorandum of law;

3) Defendants' motion for reconsideration of the court's January 5, 1996 ruling regarding Professor Shevchenko is GRANTED IN PART, and Professor Shevchenko will be precluded from testifying as to quantified dose estimates based upon the tree study and cytogenetic analysis;

4) Defendants' motion for reconsideration of the court's January 5, 1996 ruling regarding Professor Shevchenko is DENIED IN PART, and Professor Shevchenko will be permitted to testify as to the results of the cytogenetic analysis and as to his observations of morphological damage to trees in the TMI area;

5) Defendants' motion in limine to exclude Plaintiffs' dose experts is DENIED IN PART as to the Wing cancer incidence study, and Dr. Wing will be permitted to testify to the extent stated in the accompanying memorandum of law, and this court's memorandum of law dated January 5, 1996;

6) Defendants' motion in limine to exclude Plaintiffs' dose experts is GRANTED as to Dr. Olga Tarasenko;

7) Defendants' motion in limine to exclude Plaintiffs' experts on medical causation is GRANTED as to Dr. Bruce Molholt;

8) Defendants' motion in limine to exclude Plaintiffs' experts on medical causation is DENIED as to Dr. Luis Fajardo;

9) The court's orders directing that no filings be made without express leave of court remain in effect until the balance of the court's in limine ruling is issued.

APPENDIX F — MEMORANDUM AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF PENNSYLVANIA DATED APRIL 5, 1996

In re TMI LITIGATION CASES
CONSOLIDATED II.
This Document Relates to All Plaintiffs.

Civil Action No. 1:CV-88-1452.

United States District Court,
M.D. Pennsylvania.

April 5, 1996.

* * *

MEMORANDUM

RAMBO, Chief Judge.

On April 2, 1996, the court issued a memorandum of law ruling in part on Defendants' motion in limine to exclude Plaintiffs' medical causation experts. Remaining before the court is the balance of that motion, including challenges to the proffered testimony of Thomas Winters, Theodor Sterling, Sigmund Zackrzewski, David Lochbaum, Joseph Cardinale and Jose Galindo, Jr. A statement of the factual background of the case and discussion of the legal standards governing the admission of expert scientific testimony can be found in this court's memorandum of law dated January 6. 1996. In re TMI Litigation Cases Consolidated II, 911 F.Supp. 775 (M.D.Pa.1996). The court will now reach the remaining in limine challenges.

Appendix F

I. Dr. Thomas Winters

Dr. Winters is a medical doctor, board certified in internal and occupational medicine, (Tr. at 1206), and eligible for certification in infectious diseases. He is the medical director for employee health, and director of a clinic on occupational medicine at Carney Hospital in Boston, Massachusetts. (Tr. at 1199, 1211.) Dr. Winters is also a Clinical Associate Professor of Medicine at the Boston University School of Medicine and a Visiting Lecturer in Occupational Medicine at the Harvard University School of Public Health. (2/27/95 Winters Rpt. at 1.) Based upon his review of all of the test Plaintiffs' medical records, and his personal examination of the living test Plaintiffs, Dr. Winters offers his opinion that each of the test Plaintiffs' neoplasms were caused by their exposure to ionizing radiation during the TMI accident. Defendants' specific challenges relating to the admissibility of Dr. Winters' proffered testimony will be addressed in the context of the court's Daubert/Paoli II analysis.

A. The Daubert/Paoli II Analysis

1. Is the Methodology Based Upon a Testable Hypothesis?

When asked during his deposition whether he started his evaluation with a hypothesis, Dr. Winters replied that he "start[ed] with no hypothesis." (6/23/95 Winters Dep. at 72.) Dr. Winters distinguished his study from general epidemiological studies and stated that without a hypothesis, he simply applied his methodology to each case. (Id. at 73.)

According to the Paoli II court, "differential diagnosis can be considered to involve the testing of a falsifiable hypothesis . . . through an attempt to rule out alternative causes." Paoli II, 35 F.3d 717, 758 (3d Cir.1994). To determine whether Dr. Winters tested his hypothesis, the court must determine whether he performed a differential diagnosis. According to Dr. Winters' deposition testimony, he reviewed the medical records of all of the test Plaintiffs and performed physical examinations upon those test Plaintiffs that are still living. (6/23/95 Winters Dep. at 72, 73, 81-82.) Pursuant to Paoli II, Dr. Winters examined the information necessary to make a differential diagnosis. Paoli II, 35 F.3d at 762. As such, whether or not Dr. Winters realized it, his differential diagnosis was essentially an attempt to verify or falsify the hypothesis that the TMI Plaintiffs developed their neoplasms as a result of exposure to ionizing radiation during the TMI accident. The court finds that to the extent that it is relevant to making a differential diagnosis, Dr. Winters' methodology is based upon a testable hypothesis. This factor will weigh in favor of the admission of the proffered testimony.

2. Has the Methodology Been Subject to Peer Review?

At the in limine hearing, Dr. Winters testified that his methodology, as applied in a radiation case, has not been subject to peer review. (Tr. at 1355-56.) Insofar as Dr. Winters methodology is a differential diagnosis, the Third Circuit has recognized that "differential diagnosis generally is a technique that has widespread acceptance in the medical community, has been subject to peer review, and does not frequently lead to incorrect results. . . ." Despite the general

presumption that a differential diagnosis methodology has been subject to peer review, Dr. Winters testified that his radiation causation differential diagnosis has not been subject to peer review. In light of Paoli II the court finds this factor to be of diminished relevance in the context of a differential diagnosis. However, to the extent that it is relevant, this factor will weigh against the admission of the proffered testimony.

3. Is There a Known or Potential Rate of Error?

Although a differential diagnosis "does not frequently lead to incorrect results," Paoli II, 35 F.3d at 758, "to the extent that a doctor utilizes standard diagnostic techniques in gathering this information, the more likely" the methodology will be found to be reliable. Id. Defendants' arguments with respect to the potential rate of error in Dr. Winters' methodology relate to the diagnostic techniques that he used and failed to use.[1] First, Defendants contend that

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1. A hypothetical that appears in a footnote in Paoli II, is instructive:

> We note that it is not only simple cases that could justify a finding of reliability absent employment of a significant number of diagnostic techniques. Imagine a patient who comes to a physician with medical records demonstrating illness A known to be strongly associated with chemical X and evidence of exposure to that chemical. Also, imagine that there are other chemicals, foods, or other substances to which the patient has been exposed which sometimes, though much less frequently, cause this same illness. With a basic understanding of

(Cont'd)

Dr. Winters based his opinion in part upon the unfounded assumption that Plaintiffs were exposed to 10 to 300 rems of radiation, and that exposure anywhere in that range would produce the kinds of effects that were observed. During his deposition, Dr. Winters explained that he "knew the dose was above a hundred rems, and figured that even if it dropped down to the 50- or 10-rem area, [his] . . . opinion would still be the same." (6/23/95 Winters Dep. at 80.) It is unclear how Dr. Winters "knew" the dose rate. In his deposition Dr. Winters indicated that prior to conducting his analysis he "had reviewed the Hatch articles in American Journal of Public Health, American Journal of Epidemiology . . . [and] had reviewed pictures of trees and had heard that Dr. Gunckel had evaluated and Dr. Shevchenko had looked at dendritic samples that showed a significant dose of radiation."[2] (Id. at 76.)

(Cont'd)

> probabilities, a physician might very well be able to reliably conclude that a person exposed to chemical X was more likely than not to have contracted illness A as a result of that exposure than as a result of any other cause.

Paoli II, 35 F.3d at 760 n. 30 (emphasis added). From this hypothetical the court infers that evidence of exposure is important to the analysis, and that where a causal analysis is made without proper evidence of exposure, conclusions generated by the analysis would be potentially unreliable.

2. Contrary to both his original report and his deposition testimony, Dr. Winters' testimony at the in limine hearing was as follows:

(Cont'd)

Appendix F

Dr. Winters' method of gathering exposure and dose information introduce a potentially high rate of error into his analysis. The scientific literature supports the proposition that below a dose of 10 rems, there is no direct evidence of a causal relationship between exposure to ionizing radiation and cancer induction. National Research Council, Committee on the Biological Effects of Ionizing Radiation, Health Effects of Exposure to Low Levels of Ionizing Radiation at 7 (National Academy Press 1990) ("BEIR V") (noting that "[a]ssessment of the carcinogenic risks that may be associated with low doses of radiation entails extrapolation from effects observed at doses larger than 0.1 Gy [(10 rems)] and is based on assumptions about the relevant dose effect relationships and the underlying mechanisms of carcinogenesis"). To the extent that Dr. Winters presumed a dose of greater than 10 rem, without having gathered reliable data to support that presumption, his differential diagnosis has a high probability of being incorrect.

(Cont'd)

> The critical steps start with defining the exposure which I did . . . using data from Vergeiner, the meteorologic data, Beyea's dispersion dosimetry from the Hatch-Susser article, Shevchenko's literature supporting the abnormalities of trees and the dicentrics, Tarasenko's review which delineated T-lymphocyte defects in the study population, and finally Daniel who is a defendant witness . . .

(Tr. at 1315.) The testimony appears to be consistent with his supplemental affidavit, filed February 26, 1996. The court has, however, excluded all reports and supplemental affidavits filed after January 5, 1996. Accordingly, the court will consider only the timely filed report and deposition testimony.

Appendix F

Next, Defendants contend that data from the study of populations exposed to radiation indicate that where a study fails to consider factors such as a specific organ dose, the effect of a person's age at the time of exposure, the time since exposure, and the effect of the sex of the person on their risk of developing the type of cancer they exhibit, any conclusion regarding a causal relation between radiation exposure and a given health outcome is subject to substantial error. The International Commission on Radiation Protection ("ICRP")[3] has observed that "[t]he relationship between the probability of stochastic[4] effects and equivalent dose is found also to depend on the organ or tissue irradiated. It is therefore

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3. The ICRP, initially established in 1928, began making recommendations regarding radiological protection in 1977. ICRP Publication 60, Annals of the ICRP, "1990 Recommendations of the International Commission on Radiological Protection" vii, 1 (Pergamon Press 1991) ("ICRP Pub. 60"). The ICRP defines the aims of their recommendations as follows:

> (a) to take account of new biological information and of trends in the setting of safety standards,
>
> (b) to improve the presentation of the recommendations,
>
> (c) to maintain as much stability in the recommendations as is consistent with new information.

ICRP Pub. 60 at vii.

4. "Stochastic effects are those which result from alterations in normal cells caused by an ionising [sic] radiation event which is assumed to have a low probability of occurrence in cells at low doses." ICRP No. 60 at 106.

appropriate to define a further quantity, derived from equivalent dose, to indicate the combination of different doses to several different tissues[5] in a way which is likely to correlate well with the total of stochastic effects." ICRP Pub. 60, Annals of the ICRP, "1990 Recommendations of the International Commission on Radiological Protection" 6 (Pergamon Press 1991) (footnote added). This ICRP report also supports Defendants' assertion that sex and age at the time of exposure are "[b]iological factors affecting cancer induction" following exposure to ionizing radiation, that should be considered when making a causal inference regarding radiation exposure and cancer induction. Id. at 120-22.

The court, as it did with this component of Dr. Fajardo's methodology, finds it difficult to quantify the effect that the omission of the referenced data might have had upon the overall analysis. It is apparent that the omission of this data introduced at least a moderately high potential rate of error into the final diagnosis. In Paoli II, the Third Circuit held that where a physician offered a differential diagnosis which found a causal link between PCB exposure and subsequent health effects, and where the defendants then offered an alternative cause for the plaintiffs' health effects, the expert "had to offer a good explanation as to why their conclusion remained reliable." Paoli II, 35 F.3d at 762. To a limited extent, the court finds Dr. Winters' failure to consider certain data, Defendants' direct challenge on that subject, and Dr. Winters' subsequent failure to offer a "good explanation" for the omission to be analogous to the Paoli II scenario.

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5. This is commonly referred to as the organ or tissue dose.

However, where the Third Circuit has clearly expressed its opinion as to the general reliability of differential diagnosis, and the more liberal standard under which this court must evaluate such a diagnosis, the court is finds that the failure to consider certain potentially relevant data goes to the weight of the testimony.

Because the court is unable to quantify the effect that Dr. Winters' omissions had upon the reliability of his findings, the court will weigh this factor neither in favor nor against the admission of the proffered testimony.

4. Were There Standards Controlling the Technique's Operation?

Defendants contend that the lack of standards controlling Dr. Winters' differential diagnosis is evidenced by his "consistently ignor[ing] epidemiologic data that was not consistent with his ultimate conclusions on causation," and his misplaced reliance on toxicological texts as providing the standards governing his methodological approach. (Defs.' Findings at 130-31.) During his deposition, Dr. Winters provided the following statement of his methodology:

> I used the methodology of occupational, standard toxicology, occupational health evaluations, where you look at a condition, you look at the dose, the dose response, you make sure there's adequate latency period, you make sure there are no other confounding contributing factors. You make sure that the illness is, in fact, caused, or the disease is, in fact, caused by the agent, which

> is radiation in this case, and you make a logical deduction at the end of that.

(6/23/95 Winters Dep. at 72.) The court finds Dr. Winters' failure to consider the importance of calculating a specific organ dose to evidence an absence of a standard controlling the operation of his technique. However, the court also finds evidence on the record that Dr. Winters did employ some important standards such as considering relevant latency periods and considering possible confounding factors. Accordingly, the court finds that because there is evidence that some important standards were employed, Defendants' challenges go to the weight, and not the admissibility, of the proffered testimony. This factor will weigh in favor of the admission of the proffered testimony.

5. Is the Methodology Generally Accepted?

It is unquestionable that as a general proposition, the use of differential diagnosis in the medical field is well accepted. The issue, though, is whether it is generally accepted to infer a causal relationship between a possible exposure to ionizing radiation and a subsequent health effect based solely upon a differential diagnosis. In connection with its evaluation of the Fajardo proffer, the court found that such an inference is not generally accepted. In re TMI, 922 F.Supp. 997, 1036 (M.D.Pa.1996) (quoting the NCRP's finding that " 'it is not possible, on the basis of medical evaluation, to unequivocally prove or disprove a claim that a specific malignancy was caused by a specific radiation exposure' "). Despite this finding, the court found this factor to weigh in favor of the admission of the Fajardo proffer.

The court found that through his report and testimony, Dr. Fajardo did not represent that he had "unequivocally prove[n]" that Plaintiffs' neoplasms were causally related to radiation exposure during the TMI accident. Dr. Fajardo's conclusion is based upon a presumption that other of Plaintiffs' experts will establish the actual exposure to the requisite dose.[6] Accordingly, insofar as the court must

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6. Plaintiffs have often advanced the argument that their expert testimony should be viewed as a cohesive whole rather than segmented. As a general proposition, the court agrees that, at their peril, Plaintiffs are free to make a tactical decision to intertwine the testimony of various experts. This approach has proven to be detrimental to Plaintiffs with respect to several of their dose experts. In several instances, key assumptions made by expert A, upon which expert B's testimony was based, were found to be scientifically unreliable. Thus, the exclusion of expert A's testimony left a gap in the data upon which expert B relied. This gap often contributed to the court's finding that expert B's testimony was scientifically unreliable.

Dr. Fajardo's proffered testimony provides an example of a situation where Plaintiffs' tactical decision works. In theory, Plaintiffs can present certain experts to testify as to dose and others to testify as to causation. It is not unreasonable, in theory, for a causation expert to make his or her opinion contingent upon a different expert establishing a given dose. To the extent that Plaintiffs fail to establish dose at the summary judgment stage or trial, the court would have grounds to preclude medical causation testimony based upon the presumption that Plaintiffs were exposed to a given dose. At this juncture, however, the court is not ruling upon the sufficiency of Plaintiffs' evidence. Thus, for now, it is appropriate for the court to accept medical causation testimony that is based upon the presumption that other experts will establish a threshold dose.

presume at this stage that Dr. Winters' proffered testimony will be supported at trial by evidence that the test Plaintiffs were exposed to in excess of 10 rems of ionizing radiation; and, insofar as other experts will present testimony that provides "another basis for judgment as to causation," NCRP Stmt. No. 7 at 1, the court finds that this factor weighs in favor of the admission of the proffered testimony.

6. Is There a Relationship Between the Technique and Methods That are Established to be Reliable?

Defendants' argue that Dr. Winters' methodology bears little resemblance to methods established to be reliable. While Dr. Winters' methodology does not closely resemble established methods, it does bear some resemblance. To the extent that Dr. Winters has made a medical differential diagnosis, his methodology comports closely with established and reliable methods. Conversely, to the extent that in making a causal inference he is actually engaged in a risk assessment, Dr. Winters' methodology bears little resemblance to established methods. On the balance, the court finds that because his methodology bears some relationship to established methods, this factor weighs in favor of the admission of the proffered testimony.

7. What are the Qualifications of the Expert Based Upon the Methodology?

Defendants argue that Dr. Winters is not qualified to testify as an expert in radiation health effects. Specifically, Defendants contend that Dr. Winters' review of scientific

literature on the epidemiologic studies of populations exposed to radiation does not establish him as an expert in the field. In addition, Defendants note that one other district court has found that Dr. Winters was "not qualified to testify on either the general or specific causal relationship between radiation and the induction of [acute lymphocytic leukemia]." Whiting v. Boston Edison Co., 891 F.Supp. 12, 25 (D.Ma.1995). The Third Circuit recently reaffirmed its liberal approach regarding the qualifications factor of the Rule 702 analysis in Holbrook v. Lykes Bros. Steamship Co., 80 F.3d 777, 782 (3d Cir.1996). Specifically, the Third Circuit explained that:

> Because of our liberal approach to admitting expert testimony, most arguments about an expert's qualifications relate more to the weight to be given the expert's testimony, than to its admissibility. Thus, witnesses may be competent to testify as experts even though they may not, in the court's eyes, be the "best" qualified. Who is "best" qualified is a matter of weight upon which reasonable jurors may disagree. . . . Following this logic, it is an abuse of discretion to exclude testimony simply because the trial court does not deem the proposed expert to be the best qualified or because the proposed expert does not have the specialization that the court considers most appropriate.

Holbrook, 80 F.3d at 782. Dr. Winters certainly may not be the "best" qualified expert in this area. Moreover, it cannot be taken lightly that he has been precluded from giving the

same type of testimony in other litigation on the basis of his lack of qualifications. Nevertheless, Dr. Winters is a practicing physician who has demonstrated at least a basic knowledge of the relevant scientific principles. Pursuant to Holbrook and Paoli II this court is bound to liberally construe the qualifications prong of the Rule 702 analysis. Accordingly, this factor weighs in favor of the admission of the proffered testimony.

8. Are There Non-Judicial Uses of the Methodology?

Dr. Winters performs differential diagnoses in a variety of settings connected with his medical practice. It is questionable whether the specific methodology used in this case to determine whether radiation caused specific cancers has been employed outside of litigation. This factor will weigh neither in favor nor against the admission of the proffered testimony.

9. Conclusion

Based upon its Rule 702 reliability analysis, the court finds the proffered testimony of Dr. Winters' to be scientifically reliable.

B. Rule 702 Fit, Rule 703 and Rule 403 Analyses

If permitted, Dr. Winters will offer his opinion that each of the test Plaintiffs' neoplasms were induced by their exposure to ionizing radiation during the Three Mile Island Accident. Presuming that Plaintiffs present evidence that

corroborates Dr. Winters' assumption regarding the dose of radiation received by the test Plaintiffs, Dr. Winters' causation testimony will have the requisite "fit" with the case. At this stage, the court finds that Dr. Winters' proffered testimony "fits."[7] With respect to Rule 703, the court finds that Dr. Winters relied upon the type of data that a medical professional would rely upon in making a differential diagnosis. Defendants' challenges with respect to data that Dr. Winters failed to consider go to the weight of his testimony. Finally, the court finds that the proffered testimony is not so confusing as to warrant exclusion pursuant to Rule 403. Based upon the foregoing, the court will admit the proffered testimony of Dr. Winters.

II. Dr. Theodor Sterling

Dr. Sterling is a Professor on the faculty of Applied Sciences in the School of Computing Science at Simon Fraser University in Burnaby, British Columbia, Canada. Before the court is Dr. Sterling's initial report, dated April 25, 1995, and a supplemental affidavit, dated February 2, 1996. In accordance with its memorandum of law dated April 2, 1996, the court will exclude Dr. Sterling's untimely 1996 affidavit. Accordingly, the court will proceed with its evaluation of the Sterling proffer based upon the timely filed report and his in limine testimony to the extent it is not beyond the scope of his report.

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7. The court reserves the right to reconsider this determination based upon the dose evidence presented to the court at either the summary judgment stage or at trial.

Appendix F

A. The Proffered Testimony

Dr. Sterling testified at the hearings that he performed an epidemiological analysis on certain groups of data relating to the TMI area. (Tr. at 1090.) In the introduction to his report, Dr. Sterling gives the following brief discussion of each cohort and the statistical analysis performed on the cohort:

> The Hesteco Garment Workers: A cohort of 69 women employed by Hesteco Manufacturing Co. and present at the factory premises at the time of the accident. Ten women have developed cancer since then. This number of cancers is greater than would be expected had the cohort developed cancer at the same incidence rate as a comparable group of women selected from the general population.
>
> . . . . .
>
> The Harrisburg School Children: A cohort consisting of 1991 students attending four Harrisburg elementary schools at the time of the accident. At least six of these students have developed cancer. This number of cancers is greater than would be expected had the cohort developed cancer at the same incidence rate as a comparable group of children selected from the general population.
>
> The Ten Mile Cohort: A cohort consisting of all persons under the age of 25 years at the time of

> the accident, living within a ten mile radius of Three Mile Island. This cohort showed a dramatic increase in leukemia incidence rates following the accident.
>
> First Trimester Infants: The cohort of infants born to mothers who were in the first trimester of pregnancy at the time of the accident, and who lived within a 10 Mile radius of Three Mile Island. This cohort shows a greater incidence of congenital malformations than a cohort of infants born to mothers of the same region who became pregnant after the accident, and than a cohort of infants born in Atlanta from 1968 to 1979.

4/25/95 Sterling Rpt. at 3-4. Dr. Sterling's report also contains an analysis of a cohort consisting of high school softball players. Plaintiffs have withdrawn this cohort from the proffered testimony.

B. Discussion

The Federal Judicial Center's Reference Manual on Scientific Evidence provides a sound starting point for the court's discussion of Dr. Sterling's proffered testimony. The manual makes the following observations regarding epidemiological analyses:

> While the findings of epidemiology always involve a measure of uncertainty, systematic methods for assessing the characteristics of persons included in the study and their risk of

> disease can be used to help rule out known sources of bias and error.
>
> The epidemiologist uses sample size calculations and inclusion and exclusion criteria for identifying exposed and unexposed study groups . . . to reduce potential error and bias in a study. These methods and techniques of epidemiology provide a means of assessing the relationship between a disease and its causes. . . . [T]he precision of epidemiological methods is based on the stability of studying large numbers of people. There should be a sufficiently large number of subjects, so that a small change in the number of people with the disease does not appreciably affect the results of the study.

Ref.Man. at 127. With respect to the design of a cohort study, the Reference Manual notes that "[a] list of criteria for inclusion in and exclusion from the study must be articulated by the researcher. These criteria should be documented clearly before the subjects are recruited for the study to ensure that no overt or covert biases enter into the selection process. Such biases could lead to erroneous inferences regarding the selection process." Id. at 138. The Third Circuit has recognized the errors that can result from improper data collection. In DeLuca v. Merrell Dow Pharmaceuticals, Inc., 911 F.2d 941, 955 (3d Cir.1990), cert. denied, 510 U.S. 1044, 114 S.Ct. 691, 126 L.Ed.2d 658 (1994), the court noted in dicta that "[f]aulty data collection resulting from design or execution flaws, for example, can create a much greater risk of error than sampling error. Thus, a poorly conceived or

conducted study that disproves the null hypothesis at a .01 level of significance may be far less reliable than a well conceived and conducted study that is significant at a .1 level." Id. The court went on to hold that "any assessment of reliability under Section 702 should be conducted with an eye to all the risks of error posed by the proffered evidence." Id. It is with this "eye toward risks of error" that the court turns to its analysis of the Sterling proffer.

The court's review of the Sterling proffer, including his timely report and in limine hearing testimony, raises troubling questions about Dr. Sterling's study design or lack thereof. Dr. Sterling's report does not include a discussion of his study design. On cross examination at the hearing, Dr. Sterling testified as follows:

> Q How did you go about looking for the groups that you analyzed here?
>
> A We were contacted by Mrs. Aamodt and Mr. Aamodt who had done some additional — had some done work, and we were asked to calculate risks for these groups.
>
> Q So they selected the groups and provided you with the data, and then you did the statistical calculations regarding the data that they provided?
>
> A That is correct.

(Tr. at 1092.) Thus, prior to receiving the data, Dr. Sterling had no role in the conduct of the study. Were Mr. and Mrs.

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Aamodt epidemiologists who had independently developed a study design which included an articulation of their selection criteria, the court would not find Dr. Sterling's lack of involvement to pose a problem. To the court's knowledge, however, the Aamodts are neither epidemiologists nor experts in any other scientific discipline. The Aamodts have been identified as "consultants" to Plaintiffs in the context of this litigation. They are not listed as expert witnesses and have not supplied any expert reports for this case. Accordingly, Dr. Sterling's reliance upon the Aamodts to develop a selection criteria for his statistical analysis poses a grave problem.

First, there is no evidence on the record from which the court can make any judgment regarding the qualifications of the Aamodts to create and execute the selection portion of an epidemiological study design. Second, and more important, because there is no record evidence which describes what the Aamodts' selection criteria were, Defendants would be unable to cross examine on this important issue. Therefore, even if the court were to stretch the liberal admission standard of Rule 702 to its limit by admitting the testimony, the purpose of the liberal admission policy would nevertheless be frustrated. That is, Defendants would not have the opportunity to influence the amount of weight that the jury might accord to the study because there is no record of evidence from which they could cull their cross examination of Dr. Sterling regarding the selection criteria for the study. Finally, the court finds the lack of a clearly articulated selection criteria for the statistical analysis subjects the results to an enormous potential rate of error.

Based upon the foregoing, the court will exclude the proffered testimony as scientifically unreliable pursuant to Rule 702. In addition to the study's lack of scientific reliability, the court finds, pursuant to Rule 703, that Dr. Sterling improperly relied upon data that other experts in the field would find to be unreliable.

III. Dr. Sigmund Zakrzewski

Dr. Zakrzewski has a Ph.D. in biochemistry, and has spent his entire career in cancer research. Although he is now retired, Dr. Zakrzewski spent most of his career as a cancer researcher at the Roswell Park Cancer Institute in Buffalo, New York.[8] Dr. Zakrzewski indicates that he was contacted by Plaintiffs in 1993 and asked "to review cases of different types of cancer that erupted in the proximity of the Three Mile Island (TMI) nuclear power plant, allegedly due to the release of radioactivity resulting from the nuclear accident at that plant on March 28, 1979." 9/15/95 Zakrzewski Aff. at 1. Before the court are Dr. Zakrzewski's timely filed report, a supplemental affidavit filed February 1, 1996, his deposition testimony, and his in limine hearing testimony. In accordance with this court's memorandum of law dated April 2, 1996, the court will consider only the timely filed report, the deposition testimony and the hearing testimony to the extent that it does not exceed the scope of the report or deposition testimony.

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8. Dr. Zakrzewski was first associated with the Department of Experimental Therapeutics, he later moved to the Department of Clinical Pharmacology. During his time at Roswell Park, Dr. Zakrzewski was elevated from the position of Senior Cancer Research Scientist to Associate Research Scientist, and then to the position of Principal Cancer Research Scientist.

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A. The Proffered Testimony

In his report, Dr. Zakrzewski concludes that "the four cases of leukemia discussed here [(Plaintiffs Beam, Obercash, Villella and Macri)] were most likely caused by exposure to radiation released during the TMI accident," 9/15/95 Zakrzewski Rpt. at 4, "the three cases of the thyroid cancer [(Plaintiffs Dolan, Gaughan, and Peterson)] were most likely caused by a radioactive fallout resulting from the accident at TMI," id. at 5, and "the most likely cause of the plaintiff's osteosarcoma [(Plaintiff Ward)] is exposure to a radioactive fallout originating from the nuclear accident at TMI. In the two other cases, i.e., breast cancer ([Plaintiff Hickernell]) and ovarian cancer ([Plaintiff Hilt]) the whole body exposure to radiation are the most likely causes." Id. at 7. At the outset of his report, Dr. Zakrzewski lists a number of factors which he considered in making his evaluation. These factors are as follows:

1. The type of cancer;

2. age of the victims at the time of the accident;

3. occupation at the time of the accident;

4. whereabouts of the victims at the time of the accident;

5. latency period between alleged exposure and diagnosis;

6. other cancer cases in the neighborhood of the plaintiff's residence or the place of business;

7. possible exposure to carcinogens other than radiation;

8. prior exposure to medical radiation;

9. any evidence, other than the victims' disease indicating possibility of exposure to ionizing radiation.[9]

9/15/95 Zakrzewski Rpt. at 2. Further Dr. Zakrzewski notes that because he is not a physician he did not review the test Plaintiffs' medical records. Instead he "relied . . . on the diagnosis of the victims' physicians." Id. At the hearing, it was disclosed that the only data upon which Dr. Zakrzewski relied was a "summary sheet"[10] provided to him for each test Plaintiff. (Tr. at 1146, 1167.) Dr. Zakrzewski further testified that the summary sheets were prepared by Plaintiffs' counsel and transmitted to him by Mrs. Aamodt. (6/13/95 Zakrzewski Dep. at 53, 61; Tr. at 1166-67.) Finally, Dr. Zakrzewski noted that he did not formulate a methodology

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9. Dr. Zakrzewski testified that with the exception of the leukemia cases he relied "solely on the information [he] . . . had from Dr. Shevchenko with regard to . . . dose." (Tr. at 1187.) Dr. Zakrzewski paid particular attention to damaged tree evidence. However when asked "[s]o at the time that you wrote your report and came to your conclusions that are contained in your report, you didn't have a map showing locations of the trees; you had the information on the summary sheets that told you there were trees in the vicinity][?]" Dr. Zakrzewski replied "You are correct." (Tr. at 1188.)

10. The summary sheets were marked as Defendants' exhibit 181 during the in limine hearings.

first and then request appropriate data from Plaintiffs' counsel; rather he was provided with data first and then constructed his methodology. (Tr. at 1167.)

B. Discussion

1. Qualifications

Plaintiffs offered Dr. Zakrzewski as an expert on risk assessment and environmental toxicology. (Tr. at 1126.) Defendants vigorously contend that Dr. Zakrzewski is not qualified to render an opinion on the medical causation issues in any of the test cases. Most of Defendants' argument centers around Dr. Zakrzewski's lack of formal qualifications in the area of toxicology and risk assessment. Defendants also argue that although Dr. Zakrzewski has almost thirty-seven years of experience in the field of cancer research, "none of [Dr.] Zakrzewski's research experience involved the health effects of radiation or radioactive compounds 'of the sort which we are considering here.' " (Defs.' Findings at 137 (quoting Tr. at 1128, 1124).) Pursuant to the Third Circuit's recent ruling in Holbrook, the court finds that Defendants' challenges go to weight rather than admissibility. Although Dr. Zakrzewski does not have specialized expertise regarding the health effects of radiation, he is an experienced cancer researcher who has had some continuing education, albeit a brief education, in the area of toxicology.[11] As such, he meets the threshold requirement for qualification as an expert.

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11. Dr. Zakrzewski attended a thirty hour summer course in toxicology at the Massachusetts Institute of Technology.

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2. Reliability of the Data

Dr. Zakrzewski's report suffers from a data problem similar to that of Dr. Sterling. Both in his deposition and at the in limine hearing, Dr. Zakrzewski testified that all of the information he utilized in forming his causation opinion was contained within the summary sheets provided to him by Mrs. Aamodt.[12] The summary sheets that Dr. Zakrzewski relied upon were admitted during the in limine hearings as Defendants' exhibit 181. The summaries are organized with the following headings: personal information, social information, injury claimed, geographical relationship to the accident,[13] evidence of exposure to the accident,[14] knowledge of post-accident health of neighbors or schoolmates,[15] other

12. At his deposition Dr. Zakrzewski indicated that although he had Plaintiffs' medical records in his possession and "looked at them," he did not draw any of his factual knowledge about Plaintiffs from the medical records because he is "not competent to review medical record[s]." 6/13/95 Zakrzewski Dep. at 60, 61 ("Q . . . [D]id you utilize factual information that you discovered in the medical records?" "A No.").

13. This section gives the Plaintiff's home and school or work address and notes the distance of each address from TMI. It is also indicates whether the Plaintiff evacuated at any time during the accident.

14. This section is comprised of anecdotal evidence. The summary poses the following questions: "Aware of metallic taste or erythema as symptoms of radiation exposure during or after the accident?", and "Aware of accident or danger of accident on the first two days so that they would have looked for symptoms of exposure?" (Defs.' Ex. 181.)

15. This section is also comprised of anecdotal evidence.

risks prior to diagnosis.[16] No evidence has been placed on the record as to how these summary sheets were created. As such, it is impossible for the court to find with any certainty that the summary sheets are reliable. The issue for the court is whether the reasonable expert, in performing a risk assessment to determine the likelihood that a given

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16. This section provides information about prior potential radiation exposure only as to some Plaintiffs. As such, Dr. Zakrzewski was unable to consider this factor in his evaluation of certain of the test Plaintiffs (e.g. Villella, Putt). Some of the summary sheets provide precise information regarding the dates, site and type of medical and dental x-rays. Others simply note that the Plaintiff had, for example, "dental x-rays" (e.g. Ward). The following colloquy is illuminating:

> Q With regard to factor number 8, prior exposure to medical radiation, you ruled it out as a potential alternative in all cases where you had information, correct?
>
> A I reviewed this dental exposure which was provided to me of some of the plaintiffs where I could calculate the extent of exposure. Some cases were just type of equipment given, so it was impossible for me to calculate it.
>
> Q And when it was impossible for you to calculate it, or when you were not provided with any information regarding prior medical exposures, you did not assess this factor in connection with your methodology here?
>
> A No. I could not.

(Tr. at 1173.)

individual's cancer was induced by radiation exposure, would base his opinion solely upon the type of data considered by Dr. Zakrzewski. The court finds that he would not.

There are several internationally respected organizations, composed of the most eminent scientists in the field, that have propagated guidelines for conducting risk assessments where there has been a known or potential exposure to ionizing radiation. See ICRP No. 60 at 114-53 (detailing these developments); Whiting, 891 F.Supp. at 15 ("The most authoritative assessments of the health effects on humans of ionizing radiation are the periodic reports issued by the National Research Council of the National Academy of Sciences Committee on the Biological Effects of Ionizing Radiation (BEIR)."); Johnston v. United States, 597 F.Supp. 374, 392 (D.Kan.1984) (noting that the NCRP and ICRP are organizations that represent the "scientific consensus" on the biological effects of ionizing radiation). Were Dr. Zakrzewski's risk assessment to bear some resemblance to any of these guidelines, it would be proper for the court to admit the proffered testimony and allow challenges regarding the differences in the methodology to be brought out on cross examination. The court is unable to find even an elementary resemblance between Dr. Zakrzewski's methodology and any of the internationally recognized methodologies.[17] Dr.

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17. For example, with respect to Plaintiff Ronald Ward, Dr. Zakrzewski testified as follows:

> Q In the case of Ronald Ward, am I right that you assumed that since he had osteosarcoma, that he had had an uptake of barium from the accident?

(Cont'd)

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(Cont'd)

A Yes. That was — that was one of the hypothesis.

Q And is that what you assume with regard to —

A Yes.

. . . . . .

Q Did you rely on any particular information regarding barium in the environment after the TMI accident?

A Yes. I relied on two sources. One was the information supplied by Mr. Aamodt. And the second I checked Kasared and Dole's toxicology chapter on radiation, where it has been stated that the cooling water for the reactors contains considerable amounts of barium.

. . . . . .

Q Doctor, my question is: Did you have environmental sampling data from the TMI environment indicating that there was barium in the environment, or any daughter products?

A No.

(Tr. at 1180-82.) The court notes that reactor coolant water contains boron. Thus, based upon Mr. Aamodt's "information" claiming that barium was released during the TMI accident, Dr. Zakrzewski concluded that Plaintiff Ward's osteosarcoma was caused by his exposure during the TMI accident. Initially, Dr. Zakrzewski attributed Plaintiff Ward's cancer to the release of radon during the

(Cont'd)

Zakrzewski used only a fraction of the data that any of these international committees point to as being essential. As such, the court is unable to find that Dr. Zakrzewski's study is based upon "good grounds."[18] During the hearings, Dr. Zakrzewski testified as to the basis of his opinion for each of the test Plaintiffs. His testimony further demonstrates the dramatic difference between Dr. Zakrzewski's risk assessment and a more traditional risk assessment. The following is an excerpt of the testimony heard by the court:

> Q In the case of Joseph Gaughan, you assumed that he was exposed to radiation from TMI because he got sick and there were damaged trees in his neighborhood; is that the basis of your assumption?
>
> A Yes, ma'am.

(Cont'd)
accident. When Dr. Zakrzewski learned that no radon was released, he altered his opinion to make barium the causative agent. That Dr. Zakrzewski changed his opinion is only somewhat problematic. More troubling to the court in the context of the reliability analysis, is that Dr. Zakrzewski would attribute the cancer to exposure to radon during the TMI accident without knowing whether radon was even released during the accident.

18. Defendants also challenge Dr. Zakrzewski's use and understanding of the concept of latency periods. Defendants argue that the latency periods assumed by Dr. Zakrzewski are significantly lower than the latency periods recognized by the literature. Because the court will find Dr. Zakrzewski's testimony to be inadmissible on other grounds, it will not reach the merits of Defendants' latency period argument.

Q And in the case of Lori Dolan, you assumed that she was exposed to radiation from TMI on the basis of damaged trees in her area, correct?

A Yes.

Q In the case of Jolene Peterson, you assumed that she was exposed to radiation from TMI on the basis that her mother reported a metallic taste, that her mother had erythema, and that there were damaged trees somewhere near her; is that correct?

A That's correct.

. . . . . .

Q When you wrote the report, did you study specifically where the damaged trees were in relation to Jolene Peterson's work or home address?

A No.

(Tr. at 1182-83.)

Because the study is not based upon reliable data or good grounds, the court finds the study to be scientifically unreliable. The court will exclude the proffered testimony of Dr. Zakrzewski as scientifically unreliable.

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IV. David Lochbaum

Prior to this court issuing its ruling related to the first round of in limine hearings on January 5, 1996, Plaintiffs' expert Richard Webb recanted a significant portion of his proffered testimony. Due to the recantation and the court's determination that Richard Webb's proffered testimony was scientifically unreliable, the court excluded the testimony. Richard Webb was Plaintiffs' only expert prepared to testify as to the pathways for release and quantities of radioactive noble gases released from TMI during the accident. Because the court recognized that such testimony was important to Plaintiffs' case, the court permitted Plaintiffs to find an expert to testify in Dr. Webb's place. On January 22, 1996, Plaintiffs submitted the report of David Lochbaum.[19] Mr. Lochbaum has a bachelor's degree in nuclear engineering and approximately seventeen years experience in the nuclear industry. (Tr. at 1409.) His experience in the nuclear industry has been primarily with boiling water reactors.[20] (Tr. at 1411.)

Plaintiffs contend that David Lochbaum will testify that "significantly more than 10 million curies of noble gases

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19. Prior to the first round of in limine hearings, David Lochbaum had submitted a report detailing his opinion that the Webb source term analysis was scientifically valid. The court excluded the report, without reaching the merits of a Daubert/Paoli II analysis, because following the Webb recantation, David Lochbaum's report did not have the requisite Rule 702 "fit" with the litigation.

20. The TMI-2 reactor is a pressurized water reactor, nevertheless, the court finds Mr. Lochbaum's broad experience to qualify him to testify as an expert.

reached the environment as a result of the TMI-II accident." (Pls.' Findings at 32.)[21] Mr. Lochbaum reaches this conclusion based upon his analysis of potential pathways of release through the TMI-2 reactor and connected buildings. According to Mr. Lochbaum, "the purpose of [his] . . . evaluation was to examine the role of the letdown line in the release of noble gases to the environment. The sustained use of the letdown line enabled radioactive noble gases to be removed from the reactor coolant system and containment into equipment within the auxiliary building. Noble gases were released from the auxiliary building equipment, which was not designed to retain significant volumes of highly radioactive gases." (1/22/96 Lochbaum Rpt. at 1.)

At the in limine hearing, Mr. Lochbaum testified that after his review of the pertinent data he found that he did "not believe that there was evidence of a blowout." (Tr. at 1455.) He proceeded to testify as follows:

> [I]f a blowout occurred, its duration was of limited length. It would have been on the order of minutes as opposed to the entire two- or three-hour

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21. Defendants' challenge Mr. Lochbaum's testimony, to the extent it may be offered on rebuttal, on the grounds that the testimony is based upon a misunderstanding of the source terms used by Defense experts Akers and Daniel, and because it "proceeds from a misunderstanding of the two different kinds of analyses Daniel and Akers presented in their reports." (Defs.' Findings at 28-29.) The court finds Defendants' arguments to go to weight rather than admissibility. Accordingly, the court will not reach the merits of these arguments.

> duration of the third window,[22] for example. A short duration blowout would still have been significant because of the high gas concentrated transport that would have occurred.

(Tr. at 1455-56 (footnote added).) Thus, the court views Mr. Lochbaum's testimony as being dependent upon other of Plaintiffs' experts conclusively demonstrating that significant releases of radiation in fact occurred. More specifically, standing alone, the court finds that Mr. Lochbaum's testimony would not assist the trier of fact in reaching any conclusion as to any issue in the case. If, however, Plaintiffs present other evidence that substantiates their position that a large release occurred, his theories as to how the gases left the TMI-2 reactor and entered the environment would be helpful. At this stage in the proceeding, it would be improper for the court to rule upon the sufficiency of Plaintiffs' evidence. As such, the court will admit the proffered testimony of Mr. Lochbaum subject to a later connection with substantiated dose evidence.[23]

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22. In his report Mr. Lochbaum concludes that "[t]he four prerequisites for a potential 'blowout' through the letdown line may have been satisfied on three occasions during the first day of the TMI-2 accident." (1/22/96 Lochbaum Rpt. at 8.)

23. The court notes that Defendants have not challenged the scientific reliability of Mr. Lochbaum's methodology. Instead, their challenge is based upon their belief that the testimony does not have the requisite Rule 702 fit with the instant litigation. Because Defendants have not challenged the reliability of the report, and because the court's independent Daubert/Paoli II analysis has revealed that the report is scientifically reliable, the court will not further address this issue in this memorandum of law.

Fed.R.Evid. 104(b). Should Plaintiffs be unable to "connect up" Mr. Lochbaum's testimony, it will be excluded as lacking the requisite Rule 702 "fit," and as being unhelpful to the trier of fact.

V. Dr. Joseph P. Cardinale

Dr. Cardinale is the treating physician of Plaintiff Lori Dolan. Although he was identified as an expert witness, he has not produced a report in connection with the instant litigation. Due to scheduling constraints, the court was unable to hear Dr. Cardinale's testimony at the in limine hearing. As such, the court permitted the parties to submit depositions in lieu of hearing testimony. At the deposition, Defendants made the following objection for the record:

> Today is March 6, 1996. Plaintiff's expert reports with respect to any experts they intended to offer on the issues of dose or medical causation were due on March 1, 1995, more than a year ago.
>
> There has been no written report furnished to us with respect to this witness. We have no information as to the opinions he is expected to offer, the bases for those opinions, the facts and data on which he relies or any of the other information required by Rule 26 and the Practice Orders of the Court.

(3/6/96 Cardinale Dep. at 3.) The court will sustain Defendants' objection in part. Pursuant to the discussion in § I of this court's April 2, 1996 memorandum of law, the

instant Rule 26 violation will be addressed in the context of the court's separate order to show cause why monetary sanctions should not be imposed upon certain of Plaintiffs' counsel pursuant to Rule 37 of the Federal Rules of Civil Procedure. The court will, however, admit the testimony of Dr. Cardinale for the purpose of determining whether it is scientifically reliable and based upon "good grounds." To the extent that the court finds Dr. Cardinale's testimony admissible, the court will strictly limit his testimony to that information which was expressly questioned upon and revealed during his deposition.

A. The Proffered Testimony

According to his deposition, it appears that Dr. Cardinale will testify that he is "85 percent certain" that Plaintiff Lori Dolan's thyroid cancer was induced by her exposure to ionizing radiation during the TMI accident. (3/6/96 Cardinale Dep. at 23-26.) Based upon his deposition testimony, it appears that Dr. Cardinale obtained all of his information regarding evidence of exposure from Mr. Aamodt.[24] Although not an exhaustive listing of the testimony related to his reliance on evidence provided by Mr. Aamodt, the following portions of Dr. Cardinale's testimony are illustrative:

> Q Were you supplied with any reports of witnesses?

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24. The same concerns regarding the Aamodts which have been expressed in the court's discussion of Dr. Sterling and Dr. Zakrzewski apply here.

A Yes.

Q What expert report were you supplied with?

A The main spokesman for the defendant was in charge — I forgot his name who made statements. I can look that up.

Q Would you, please. It's important.

A Okay. And then they brought a physicist over who talked to me and gave me information about different tests that they had run.

Q What was his name?

A He's from upstate New York. I can't remember his name.

Q Was his name Norman Aamodt?

A Yes.

. . . . . .

Q And what did Mr. Aamodt say that Shevchenko . . . said?

A That — one thing that stood in my mind was that there was a certain type of a pine tree that was — in Chernobyl it was stunted because of a certain exposure to radiation, and a similar pine

> tree in the path of the balloon plume from the Three Mile Island shows a stunting of the same trees. And he also reviewed studies of trees in the Three Mile Island area that shows certain gases, noble gases, that have high radiation indications to them.

(3/6/96 Cardinale Dep. at 32-33.)

. . . . .

> Q Did you do any analysis to arrive at your own estimate of what dose Lori Dolan might have received to her thyroid as a consequence of anything that happened in the TMI accident?
>
> A No.

(3/6/96 Cardinale Dep. at 40.)

As has been noted in other sections of the instant memorandum of law, a differential diagnosis which involves the physical examination of a patient or a review of pertinent medical records, is generally scientifically reliable as a matter of law. Paoli II, 35 F.3d at 758. As Lori Dolan's treating physician, Dr. Cardinale is in the position to make a reliable differential diagnosis. The court is, however troubled by the information relied upon by Dr. Cardinale. From his deposition testimony it appears that a majority of Dr. Cardinale's information regarding the amount of radiation to which the TMI population was exposed to during the accident was drawn from a one hour discussion with Mr.

Aamodt. The court has already noted that Mr. Aamodt has not been identified as an expert in this case. To the extent that Dr. Cardinale based his opinion solely upon his discussion with Mr. Aamodt, his opinion is unreliable. The indicia of trustworthiness inherent in a scientifically reliable report or study is removed where one's only knowledge of the reliable report is derived from an abstracted presentation of that report presented by a "consultant" to an interested party in the litigation.

During the deposition, Dr. Cardinale further explained the basis of his opinion as follows:

> I'm saying that the gases, the different types of radiation she was exposed to I understand was more than one. I don't know whether one gas absorbed through the lungs by breathing and another gas absorbed through the skin, whether that same hundred rads is equal to a dosage of a target of 6.5 to the thyroid. I don't know. That's were your experts will have to give an answer to that effect.
>
> As a clinician with what I have available, I am concerned that this did cause her cancer.

(3/6/96 Cardinale Dep. at 64 (emphasis added).) As Lori Dolan's treating physician, Dr. Cardinale is qualified to give an opinion as to what he believes to have been the cause of her cancer, to the extent that the evidence before him is capable of supporting such a finding. The court understands Dr. Cardinale to claim that presuming the dose of radiation

to Lori Dolan was equivalent to a target dose of 6.5 rads to the thyroid, he is 85 percent certain that her cancer was induced by that exposure to radiation. Accordingly, insofar as Plaintiffs, through other admissible evidence, can prove that Lori Dolan did receive a dose equivalent to a target dose of 6.5 rads to the thyroid, Dr. Cardinale's proffered testimony will be admitted. Fed.R.Evid. 104(b).

VI. Conclusion

Based upon the foregoing, the court will deny Defendants' motion in limine and admit the proffered testimony of Dr. Winters, Dr. Cardinale, Dr. Galindo[25] and David Lochbaum. The court will grant Defendants' motion in limine and exclude the proffered testimony of Dr. Sterling and Dr. Zakrzewski. The court notes that where it has so indicated in the body of this memorandum of law, the admissibility of Plaintiffs' medical causation experts is subject to their testimony being connected with dose testimony which establishes the dose levels that they presumed in reaching their conclusions. An appropriate order will be issued.

ORDER

In accordance with the accompanying memorandum of law, IT IS HEREBY ORDERED THAT:

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25. The court's rationale for admitting Dr. Galindo is similar to its rationale for admitting Dr. Cardinale. A brief memorandum of law with respect to Dr. Galindo will be issued April 8 or 9.

Appendix F

1) Defendants' motion in limine to exclude Plaintiffs' medical causation experts is GRANTED as to the proffered testimony of Dr. Theodor Sterling and Dr. Sigmund Zackrzewski;

2) Defendants' motion in limine to exclude Plaintiffs' medical causation experts is DENIED as to the proffered testimony of Dr. Winters, Dr. Cardinale, Dr. Galindo, and David Lochbaum, to the extent that each of their testimony is eventually connected with appropriate dose testimony pursuant to Rule 104(b) of the Federal Rules of Evidence.

APPENDIX G — MEMORANDUM OPINION OF THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF PENNSYLVANIA DATED JANUARY 5, 1996

In re TMI LITIGATION CASES
CONSOLIDATED II.
This Document Relates to All Plaintiffs.

Civil Action No. 1:CV-88-1452.

United States District Court,
M.D. Pennsylvania.

Jan. 5, 1996.

* * *

MEMORANDUM

RAMBO, Chief Judge.

Presently before the court is Defendants' motion in limine to exclude the testimony of Plaintiffs' experts on dose. Specifically, Defendants seek to exclude some or all of the testimony of the following experts: Richard Webb, David A. Lochbaum, Ignaz Vergeiner, Charles E. Armentrout, James E. Gunckel, Victor Neuwirth, Vladimir A. Shevchenko, Steven B. Wing, Douglas Crawford-Brown, and Bruce Molholt. The issues have been briefed, and the court has conducted extensive in limine hearings with respect to these experts.[1] Accordingly, Defendants' motions in limine

1. The hearings were conducted on November 13-17, 20-22, and 27-30, 1995. Prior to and during a portion of the hearings, the (Cont'd)

are ripe for disposition. In addition, the court previously issued an order, unaccompanied by a memorandum of law, with respect to the following experts: Dr. L.N. Smierennyi, Dr. Ivannovich (L.N.U.), Professor Vasilenko, Ronald Kerman, Zinovy Reyblatt, Professor Eggar, Professor Scharr, Victor Neuwirth, A. Tascev, G. Kozubov, V. Popov, A. Portman, and O. Tarasenko. This memorandum of law will set forth the court's rationale with respect to those rulings.

I. BACKGROUND

The events precipitating this litigation began to unfold at approximately 4:00 a.m. on March 28, 1979, within the Unit-2 reactor at the Three Mile Island nuclear power facility ("TMI"). The facility is located on an island in the Susquehanna River not far from Goldsboro, Pennsylvania, and the events are now known to have led to the nation's most infamous nuclear reactor accident. Despite the diligent research efforts of many persons, including persons affiliated with the instant action, many important questions remain regarding the accident. In the context of this litigation, the

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Congress and the President were unable to agree upon a federal budget. As such, portions of the federal government, including all passport offices were required to close. Due to this partial government "shutdown," Dr. Tarasenko was unable to obtain a visa to attend the hearings. The court and the parties have agreed to include Dr. Tarasenko in the next round of in limine proceedings presently scheduled to occur in February of 1996. Dr. Tarasenko's appearance at the February hearing is contingent upon her ability to obtain a visa and upon the ability of Congress and the President to agree upon a budget. If it becomes necessary, other arrangements will be made with respect to Dr. Tarasenko.

parties have endeavored to answer these questions by explaining the course of events that constitute the TMI accident. The in limine hearings conducted by the court in November of 1995 focused on the parties' theories regarding the dose of radiation emitted from TMI and allegedly received by Plaintiffs. The United States Court of Appeals for the Third Circuit has recently ruled that Defendants violated the relevant standard of care by allowing radioactive releases to occur. In re TMI, 67 F.3d 1103, 1117-18 (3d Cir.1995). The issue that remains is that of the magnitude of release for purposes of proving causation and damages. Id. at 1119. ("Defendants violated the standard of care. . . . Plaintiffs' exposures to radiation remain relevant, but only to prove causation and damages.")

Plaintiffs posit that a "blowout" occurred within the TMI Unit-2 reactor, thereby forcing high quantities of radioactive noble gases into the atmosphere. Plaintiffs have proffered the testimony of a variety of experts in support of this theory. These experts opine on subjects as diverse as nuclear reactor physics, meteorology, chromosomal abnormalities, cancer incidence, and plant biology. Through their experts, Plaintiffs seek to demonstrate that after the blowout occurred within the reactor, winds carried a dense yet narrow plume of radioactive noble gases through the atmosphere. This plume, according to Plaintiffs, made contact with land in areas north and east of TMI, with the most significant contact occurring at higher elevations.[2] Supporting their theory, Plaintiffs

2. Further, Plaintiffs contend that the plume was so narrow as to move between thermoluminescent dosimeters ("TLDs") set up as part of the TMI Radiation Environmental Monitoring Program ("REMP"). Based upon this theory, Plaintiffs' experts have unanimously questioned the accuracy of the TLDs and disregarded their readings.

contend, is evidence of tree damage, chromosome abnormalities in humans, increased cancer incidence rates, and evidence of radiation sickness in both humans and animals.

Defendants do not deny that some radioactive noble gases escaped from the reactor building during the accident. In re TMI, 67 F.3d at 1118 ("Defendants conceded that they violated § 20.106, [therefore we find] they violated their duty of care.") However, Defendants contend that Plaintiffs cannot prove either that the release was significant and dangerous or that their alleged injuries were caused by radiation. Defendants challenge Plaintiffs' proffered expert testimony on dose as lacking scientific reliability.

II. LEGAL STANDARDS FOR THE ADMISSION OF EXPERT SCIENTIFIC TESTIMONY

In Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993), the Supreme Court outlined the standards and reasoning that a district court must apply in determining whether expert scientific testimony is admissible at trial. The Third Circuit Court of Appeals has interpreted Daubert to characterize the district court's role as that of "gatekeeper." In re Paoli Railroad Yard PCB Litigation, 35 F.3d 717, 732 (3d Cir.1994) ("Paoli II"). Both Daubert and Paoli II require the district court "to act as 'gatekeeper' and to assure that the scientific methodology upon which the expert opinion is founded is reliable, i.e., that the expert's conclusion is based on good grounds (the methods and principles of science)." Paoli II, 35 F.3d at 732 (discussing Daubert). This court's

analysis of the proffered expert scientific testimony will be guided by the Third Circuit's exhaustive discussion and interpretation of Daubert in Paoli II.

Rule 702 of the Federal Rules of Evidence contains two basic requirements. The person proffered to testify as to scientific knowledge must be an expert, and the expert's proffered scientific opinion must be reliable. Paoli, 35 F.3d at 741-42. A proffered expert's qualifications should be evaluated under a rather liberal standard extending to the "substantive as well as the formal qualification[s]" of the expert. Id. at 741. Consequently, an expert who has little or no formal training in a given area may be found qualified based upon his life experience or extensive work history in that area. The reliability prong of the Rule 702 inquiry requires a district court to probe the scientific validity of proffered expert testimony. Id. at 742. When making this reliability inquiry, "a district court should take into account all of the factors listed by either Daubert or Downing[3] as well as any others that are relevant." Paoli II, 35 F.3d at 742. Specifically, the court must consider the following factors:

> (1) whether the method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted;

3. United States v. Downing, 753 F.2d 1224 (3d Cir.1985). The Supreme Court adopted much of Downing's rationale in its opinion in Daubert.

> (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; (8) the non-judicial uses to which the method has been put.

Id. at 742 n. 8.[4]

In addition to these factors, this court has apprised the parties that it also finds the following factors to be relevant:

> Falsifiability. — Scientific explanations must be capable of falsification; that is, the logical form of a hypothesis must make it amenable to empirical testing . . . [the factor is important enough that] the Supreme Court listed [it] first among its factors.
>
> Logical Consistency. — A valid hypothesis cannot be self-contradictory. . . . [I]t is evident that a hypothesis that contradicts itself is logically ill-formed and cannot be tested.
>
> . . . . .
>
> Consistency with Accepted Theories. — Scientific knowledge tends to be cumulative and

4. The court reads Paoli II as requiring it to evaluate all factors with respect to each expert's proffered testimony. Where the court finds a particular factor to be inapposite to its analysis, the court will explain the reasoning behind that decision.

> progressive, and a hypothesis that is not consistent with accepted theories should be regarded with great caution, whether or not the hypothesis ultimately proves true. . . . Though the Supreme Court rejected the Frye test, it did retain acceptance as one of the factors to be considered in evaluating science.
>
> . . . . .
>
> Precision. — Broad generalizations are far more difficult to corroborate than precise statements and have little explanatory power. . . . If severe and varied tests are the best indicator of validity, it follows that broad generalization that can account for any possible state of affairs, and thus cannot be empirically tested, are not as good.

In re TMI, No. 88-1452 (M.D.Pa. November 9, 1995) (order explaining the factors the court would consider when ruling on in limine motions) (quoting Bert Black, et al., Science and the Law in the Wake of Daubert: A New Search for Scientific Knowledge, 72 Tex.L.Rev. 715, 783-84 (1994)).

Finally, Rule 702 also requires that there be a "fit" between the testimony offered and a fact in issue. Paoli II, 35 F.3d at 743.

> " 'Fit' is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes." Thus, even if an expert's proposed testimony

> constitutes scientific knowledge, his or her testimony will be excluded if it is not scientific knowledge for purposes of the case.

Id. (quoting Daubert, 509 U.S. at __, 113 S.Ct. at 2796 (citation omitted) (emphasis in original)). Once the party seeking to admit the testimony demonstrates that the proffered testimony is reliable by a preponderance of the evidence, Paoli II, 35 F.3d at 744 n. 11 (citing Daubert), the court must evaluate the proffer pursuant to Rule 403.

Rule 403 requires the district court to consider whether the admission of proffered testimony might overwhelm or confuse the jury. As explained in Paoli II:

> [A] district court cannot exclude a scientific technique as too confusing and overwhelming simply based on its conclusion that scientific techniques by their very nature confuse and overwhelm the jury. There must be something about the particular scientific technique such as its posture of mythic infallibility that makes it especially overwhelming.

Id. at 746. Thus, "in order for a district court to exclude scientific evidence, there must be something particularly confusing about the scientific evidence at issue. . . ." Id.

With the foregoing framework in mind, the court will reach the merits of Defendants' motion in limine. Embarking on this task, the court empathizes with the plight of the United States Court of Appeals for the Ninth Circuit as they recently

ruled on the remand of Daubert. Before beginning their analysis, the Ninth Circuit reflected as follows:

> [T]hough we are largely untrained in science and certainly no match for any of the witnesses whose testimony we are reviewing, it is our responsibility to determine whether those experts' proposed testimony amounts to "scientific knowledge," constitutes "good science," and was "derived by scientific method."
>
> The task before us is more daunting still when the dispute concerns matters at the very cutting edge of scientific research, where fact meets theory and certainty dissolves into probability. As the record in this case illustrates, scientists often have vigorous and sincere disagreements as to what research methodology is proper, what should be accepted as sufficient proof for the existence of a "fact," and whether information derived by a particular method can tell us anything useful about the subject under study.
>
> Our responsibility, then, unless we badly misread the Supreme Court's opinion, is to resolve disputes among respected, well-credentialed scientists about matters squarely within their expertise, in areas where there is no scientific consensus as to what is and what is not "good science," and occasionally to reject such expert testimony because it was not "derived by scientific method."

Daubert v. Merrell Dow Pharmaceuticals, 43 F.3d 1311, 1316 (9th Cir.1995) ("Daubert II"). The scientific issues before this court are similarly daunting. As a nation, we are grateful that we have experienced only one nuclear power reactor accident of the severity of the TMI accident. In the context of this litigation, however, this translates into a lack of concrete data and knowledge regarding the specifics of such an accident. To an extent, then, this will be a journey into uncharted waters.

III. RICHARD WEBB

A. Dr. Webb's Blowout Theory

Dr. Webb, who holds a Ph.D. in Nuclear Reactor Physics, is proffered by Plaintiffs to discuss reactor operations during the accident, and to explain how fission product noble gases were released into the atmosphere. Dr. Webb's report expresses his opinion that a "hydrogen blowout" occurred within the TMI Unit-2 reactor, causing a chain reaction culminating in the atmospheric release of fission product noble gases through the Reactor Coolant System and the Letdown line.[5] Richard Webb, Analysis of the Three Mile

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5. The functioning of the coolant system in TMI's pressurized water reactor has been described as follows (internal numbers in brackets correspond to diagram attached as Exhibit A):

> The coolant system of a pressurized water reactor such as the one at Three Mile Island Unit 2 . . . is a circuit, or closed loop of distilled water with a small amount of boric acid. The water is kept during normal reactor

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operation at an average temperature of 575 degrees Fahrenheit . . . and pressures high enough (around 2200 pounds per square inch) to keep the water from boiling to steam. . . . This loop is called the primary reactor coolant system.

The primary coolant water circulates and recirculates through this loop. First it goes from the reactor core [1] — which might be thought of as a furnace where the coolant water is heated by the heat of the fission chain reaction in uranium fuel rods sheathed in cladding made of a zirconium alloy called Zircaloy — then through two "hot leg" [2] pipes which are 3 feet in diameter, to a steam generator [3]. Here in the generator the primary coolant system water transfers some of its heat to water in another, separate loop: the "secondary" or "feedwater loop." Water in the secondary loop is heated to steam without ever coming in direct contact with the primary coolant water. Having lost some of its heat, the primary coolant water then moves back via four pipes known as the "cold legs" [4] to the reactor core [1]. There it is heated once again and repeats the cycle.

The primary coolant is normally kept moving at high speed in the loop by enormous "reactor coolant pumps" [5] . . . (there are four of them).

. . . . . .

One more detail: there are two coolant loops in the TMI-2 reactor . . . , called the "A" and "B" loops. Each loop is pretty much like the other. Each has its own steam generator feeding steam to the turbine that makes

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electricity. Each loop contains two out of the four reactor coolant pumps.

. . . . . .

At a point between the reactor and the steam generator, there is a pipe leading to the bottom of a large vessel or tank called a "pressurizer" [6]. During normal operation, coolant water does not circulate back and forth through this pipe. The pressurizer is kept a little more than half full of coolant water. Above the water is a bubble, or cushion, of steam. This steam cushion at the top of the pressurizer can be made larger or smaller by slight heating or cooling of the pressurizer water just beneath it. The whole apparatus is, in fact, a means of keeping the pressure in the reactor coolant system relatively constant. When the bubble temperature and pressure are increased, it tends to push water from the pressurizer out into the primary reactor coolant loop, thus increasing the pressure in the loop. When the temperature and pressure in the pressurizer are lowered, steam condenses and the bubble shrinks. Water tends to come from the reactor coolant loop up into the pressurizer, and the overall system pressure is decreased.

In a pipe leading out of the top of the pressurizer, at the top of the space normally occupied by the steam bubble, is the "pilot operated relief valve" (PORV) [7], a very important piece of equipment to anyone who would understand the TMI-2 accident. This relief valve is designed to open automatically when the system pressure begins crowding the upper limits of safety. In theory, if the pressure in the coolant system rises very

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Island Nuclear Accident With Respect to the Release of Noble Gas Fission Product Radioactivity into the Atmosphere, June 19, 1993, at 19 (hereinafter "6/19/93 Webb Report"). The 6/19/93 Webb Report characterizes the blowout as follows:

> The lack of forced coolant flow allowed the water in the RCS [(Reactor Coolant System)] to lay and collect in lower parts of the system by gravity. The water level in the 1A cold leg pipe of the RCS is specially [sic] important; for near the base of that pipe is where the Letdown pipe is connected to the RCS. In the period between 10 hours and 13.5 hours into the accident, the 1A cold leg pipe probably emptied of water, due to venting of the reactor coolant through the PORV valve (loss of water from the RCS), and

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> abruptly, the valve will open, some of the steam will rush out (shrinking the bubble), more water will move up into the pressurizer from the primary coolant loop, and system pressure will go down. When the system pressure is back to normal, the PORV is supposed to close automatically, having returned the system to a safer pressure. If the PORV fails to close, there is a block valve [9] between it and the pressurizer that can be closed [8]. In addition to the PROV there are two other safety valves.

Mitchell Rogovin and George T. Frampton, Jr., Nuclear Regulatory Commission Inquiry Group, "Three Mile Island, A Report to the Commissioners and to the Public," NUREG/CR-1250, January, 1980 at 10-11 ("Rogovin Report").

> drainage of the water by the letdown out-flow. Because of the large drop in water inventory in the RCS by the PORV venting (during which time the injection of "make-up" water was minimal, and the make-up water was injected into the B-loop cold legs, not the A-loop cold legs), the water level in the reactor vessel probably dropped below the elevation of the inlet and outlet nozzles of the reactor vessel, thereby stopping the water flow (pour) into the 1A cold leg from the vessel, and thus allowing the 1A cold leg pipe to drain completely, due to the continuous letdown out-flow.
>
> Once the water level dropped below the intake of the Letdown pipe, the gas and water vapor in the gas space of the Reactor Coolant System could then enter the Letdown pipe (under high pressure) and blow out from the system.

(Id. at 19 (citation omitted).) Dr. Webb did not testify at the in limine hearings, although his deposition is of record. Significant portions of Dr. Webb's deposition are troubling, however, as they evidence Webb's uncertainty about his own hypothesis, methods and report. (See, e.g., Webb Dep. at 125 ("Q. What was in between the upper and lower crust?" "A. The consolidated region, yes, the consolidated region they call it. If you notice they give .2 percent is metal. So apparently I just neglected it. I don't see it in my notes.") (emphasis added); Webb Dep. at 225 ("And so I haven't really finished my investigation of that second blowout possibility or additional hydrogen generation, therefore more

release of hydrogen noble gases earlier in the accident. So I have to make it more complete or accurate about the matter of hydrogen generation.") (emphasis added); Webb Dep. at 256 ("Q. On page two of your report you say that 'A more detailed critique of Woodard's analysis has been written for inclusion as a section of this present report, but it has not been possible to type this critique in time for submission in this present report.' Did you ever type and submit that critique?" "A. Not yet. I've been involved in tremendous research. . . ."); Webb Dep. at 372 ("You got to keep in mind, this result I'm getting of release by the model is not a, is not presented and represented to be a very accurate plus or minus 1 percent sure established prediction.") (emphasis added); Webb Dep. at 529 ("Q. Now I'm really confused. Should that number be 163 or 171 or 213 or something else?" "A. You have a right to be confused. . . ." "Q. What should it be?" "A. Well, I'll, as I said, I wasn't fully, my latest calculation is the number 171 I gave you." "Q. All right." "A. Now that 213, maybe that's based on the 71 gallons per minute and I neglected to correct it. Again there was a very extreme deadline and I worked like 16-hour days and the last few days was like, like three hours' sleep, this kind of thing the last few days." (emphasis added).)

On December 6, 1995, the court became aware of a message left by Dr. Webb on the voice mail of A.H. Wilcox, co-counsel for Defendants. Through this message, Dr. Webb appears to have disavowed the underlying premise of his blowout theory. In relevant part, the message provides as follows:

> Chub Wilcox, Richard Webb calling from Germany. As a courtesy to you I want to tell you

why I haven't answered your questions at the deposition. I did prepare a letter to send you but it, in fact was ready to mail out. But I wanted to pursue questions I had of my own mathematical analysis which I've done in a very intensive and several months of deep research and I've remodeled and perfected my release models and I don't get the high releases that I got before, so it's like 25 million curies instead of 106 million curies. There's no blowout, gas blowout, that I estimate now that I had done earlier. There's a smaller one earlier in the accident that I'm predicting now, but it's during the time when the weather conditions dispersed the material much more.

So it's entirely, I always wanted to get back to the release model after I did all the dose and health effects research, get back to the release model that I did before and the deposition was an occasion to get back into that scene and pursue some of the questions I still had about which I noted in my original treatise. So I was going to make a report and submit it to the court about three weeks ago but I had to stop all that work after learning that the United States attacked Bosnia back in September . . . so I've now been working full time the last three weeks to write up a paper on constitutional law about this war to give my government.

Transcript of Voice Mail Message received by A.H. Wilcox on 12/6/95 from Dr. Richard Webb (emphasis added).

Appendix G

B. Daubert/Paoli Analysis

In defining the phrase "scientific knowledge" as it pertains to Rule 702 of the Federal Rules of Evidence, the Supreme Court noted that "the word 'knowledge' connotes more than subjective belief or unsupported speculation. The term 'applies to any body of known facts or to any body of ideas inferred from such facts or accepted as truths on good grounds.' " Daubert, 509 U.S. at __, 113 S.Ct. at 2795 (citation omitted). The Court went on to conclude that "the requirement that an expert's testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability." Id. Pursuant to Rule 104(a) of the Federal Rules of Evidence, this court must determine "whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue." Id. at __, 113 S.Ct. at 2796.

In evaluating the Webb proffer, the court encountered difficulty deciphering the substance of the proposed testimony. During June of 1993, Dr. Webb submitted a series of reports and affidavits in support of his evaluation of the TMI accident. These filings are replete with statements by Dr. Webb that they are draft versions, and that more complete reports and explanations will follow at a later date. (See, e.g., 6/19/93 Webb Report at 1 ("[I]t has not been possible to write a full treatise which would contain the complete details of the analysis and proof in the time required for submitting the Affidavit. In place of such a treatise, which can be written later, the following report of the analysis is offered. . . ."); 6/19/93 Webb Report at 24 ("I have written separate chapters . . . which contain my critical evaluation

of Daniels and Woodard treatises and the Presidents' Commission Report . . . but it has not been possible to type and print these chapters for submission of this present report.").) No "final" report was filed prior to the close of fact discovery on dose experts. Moreover, as noted above, during his deposition Dr. Webb appeared particularly uncertain of his methodology and the means by which he reached his conclusions. Dr. Webb's reports, standing alone, are inadequate to serve as a basis for finding that Dr. Webb would testify to scientific knowledge. Likewise, Dr. Webb's deposition testimony does little to solidify or clarify his analysis; in fact, it only adds to the confusion. Finally, Plaintiffs chose not to have Dr. Webb testify during the in limine hearings. As such, the court was unable to probe Dr. Webb himself regarding the uncertainties expressed in his report and deposition testimony.

Based upon the aforementioned discussion, the court was prepared to exclude the testimony of Dr. Webb as unreliable pursuant to Rules 702 and 104(a) of the Federal Rules of Evidence. Whiting v. Boston Edison Co., 891 F.Supp. 12, 18 (D.Mass.1995) (excluding expert's dose calculation based on formula of his own invention which, although superficially impressive, was "so riddled with factual inaccuracies and unproven assumptions that no reasonable jury could give his opinion credence."). Receipt of the transcript of Dr. Webb's voice mail message to Mr. Wilcox only reinforced the court's decision on this matter. As Dr. Webb himself is unable to stand behind his hypothesis or to explain how he reached his conclusions, it is impossible for the court to see how he could assist a jury in understanding the complex facts of the captioned action. Accordingly, the

court will grant Defendants' motion in limine as it applies to the proffered testimony of Dr. Webb.

IV. DAVID A. LOCHBAUM[6]

David Lochbaum is a nuclear engineer with fifteen years experience in the commercial reactor field. In his expert report, Lochbaum reviews Dr. Webb's report and reaches the conclusion that "Webb's methodology provides a valid approach for the determination of the release of fission product noble gases." (Lochbaum Rpt. at 5.) Lochbaum did not testify during the in limine hearings, and does not advance any relevant theory or hypothesis independent of his review of Dr. Webb's report. Because the court has found Dr. Webb's testimony to be unreliable and therefore inadmissible, Lochbaum's testimony no longer "fits" within the case. That Lochbaum can opine as to the methodological soundness of Dr. Webb's report, or point to flaws in Dr. Webb's methodology, is of no consequence as Dr. Webb's report will not be admitted. Based upon the foregoing, the court will grant Defendants' motion in limine to exclude the testimony of David Lochbaum as lacking the requisite Rule 702 fit with a fact in issue.

V. IGNAZ VERGEINER

Dr. Vergeiner is a meteorologist affiliated with the University of Innsbruck in Innsbruck, Austria. He holds

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6. Pursuant to this court's order dated December 14, 1995, David Lochbaum will be permitted to submit a second expert report on the issue of the alleged blowout. The following analysis pertains only to the report currently filed with the court.

undergraduate degrees in math and physics, and a Ph.D. in meteorology. For the past twenty years he has taught meteorology at both the undergraduate and graduate levels. Plaintiffs proffer Dr. Vergeiner as an expert in meteorology, specifically boundary level meteorology in alpine regions,[7] for the purpose of explaining how the alleged plume of radioactive noble gases travelled and dispersed after being released during the TMI accident. Defendants have filed a motion in limine seeking to exclude all of Dr. Vergeiner's proffered testimony.

A. Proffered Testimony

Dr. Vergeiner's testimony can be subdivided into three distinct areas. First, he has been offered to testify on the subject of boundary layer meteorology. If permitted, Dr. Vergeiner will opine regarding the weather conditions at TMI and in surrounding areas at the time of the accident and during the period immediately following the accident.[8] Based

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7. During his testimony, Dr. Vergeiner indicated that the TMI region consisted of alpine terrain. According to Dr. Vergeiner, for meteorological purposes, a mountain can be any elevation of terrain of 50 meters or more. (Tr. at 639-40, 565-66, 585.)

8. Weather conditions are critical to any plume dispersion analysis:

> Weather has a dominant influence on how and where a fallout cloud is dispersed. Important variables include the altitude to which the cloud rises and the wind speed and direction at the higher altitudes through which the cloud may rise. [For example,] [t]he degree of wind

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upon his own assumptions and source term data supplied to him by Plaintiffs' counsel,[9] Dr. Vergeiner produces estimates regarding plume dispersion. A "plume movie" and water model[10] are presented to assist Dr. Vergeiner in explaining

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> shear . . . can materially affect the dispersal of the cloud, yielding a wider, shorter spread of particles than would be observed if no wind shear was present.

Allen v. United States, 588 F.Supp. 247, 302 (D.Utah 1984) (citing S. Glasstone & P. Dolan, The Effects of Nuclear Weapons ¶¶ 9.57-9.74 (3d ed. 1977)).

9. When asked about the source of his estimated release rates, Dr. Vergeiner indicated that they were supplied to him by Plaintiffs' counsel. (Tr. at 661-62.) Additionally, Dr. Vergeiner stated that although the gross magnitude of his releases were the same as Dr. Webb's, his release times were different from Dr. Webb's. (Id.) Dr. Vergeiner was unable to explain why the time of his releases differed from those of Dr. Webb. (Id.) That an expert would be supplied source term numbers by an attorney is not in itself troubling. Yet, when that expert whole-heartily accepts the source terms without questioning their origin, attempting to verify the terms or assuring himself that they are based upon "good science," the court must question the expert's methodology. See Tulou v. Raytheon Service Co., 659 A.2d 796, 799 (Del.Super.Ct.1995) ("As with any model, the data input is crucial. . . .").

10. The water model consists of a topographical map which forms the base of a water tank. The tank is then filled with water. A dye is injected into the water and a current is run through the water to simulate air flow. In theory, the tank will demonstrate how a material will disperse in the atmosphere depending on the terrain

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his hypothesis. The "movie" is actually a series of sketches drawn by Dr. Vergeiner aimed at depicting the possible course of plume dispersion during the accident. (Tr. at 617-21, 634-36, 654.) Similarly, the water model is used to visually demonstrate how a plume might have dispersed over the TMI region during the accident. (Vergeiner Dep. at 235-38, 241.) Defendants seek to have the plume dispersion testimony excluded as scientifically unreliable and speculative. Further, Defendants seek exclusion of the plume movie and water model video on the ground that they will confuse the jury. Defendants fear that the jury will construe the examples as what did happen rather than what could have happened.

Second, Dr. Vergeiner is proffered to give his estimates of dose in certain areas surrounding TMI. These dose estimates are based upon his plume dispersion models, and on source terms given to him by Plaintiffs' counsel.

(Cont'd)

and air patterns. (See generally Tr. at 31-32 (description of the water model by Plaintiffs' counsel at the pre-hearing conference).) There are two significant design features of the proffered water model which serve to decrease its reliability and fit with the instant litigation. First, the topographical map does not accurately reflect the topography of TMI and its environs. Second, when filled to its highest level, the water in the tank just covers the highest "mountains" in the topography. Accordingly, the tank does not account for the possibility that air flow may travel over, rather than around, these "mountains." (Tr. at 33; Vergeiner Dep. at 237; Ignaz Vergeiner, Treatise on the Meteorological Aspects of the TMI-2 Accident (Part II), at 53-57 (February 1995) (discussion of the water model); IHW, Shallow Water Lab Flow Simulations Applicable to TMI-2 Accident, at 7-9 (February 1995).)

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Defendants seek to exclude this portion of Dr. Vergeiner's testimony as scientifically unreliable. During his deposition Dr. Vergeiner was unable to explain the genesis of his source terms. (Vergeiner Dep. at 248-49.) Further, at the hearing, he characterized his own models as a hybrid of art and science. (Tr. at 638.)

Finally, throughout his report, Dr. Vergeiner expresses his opinions regarding subjects wholly unrelated to meteorology. These opinions center around a general distrust of the "original" plant data from TMI, and around an apparent suspicion of the nuclear power industry. Defendants object to this testimony as being outside Dr. Vergeiner's area of expertise.

The court will analyze each of the above mentioned areas of proffered testimony under the Daubert/Paoli II framework set forth in Section II of this memorandum.

B. Daubert/Paoli Analysis

1. Is the Methodology Based Upon a Testable Hypothesis?

The logical starting point for an analysis of Dr. Vergeiner's methodology is his own somewhat convoluted discussion of that methodology. When asked during the in limine hearings whether his method consisted of a testable hypothesis, Dr. Vergeiner responded as follows:

> I would say this. When I started this work, I had no finished hypothesis. How should I? There was

no way I could have. So I started drawing together the data and forming a picture — analyzing the data and forming a picture of the weather situation. In the end, I believe what I do have you may call a hypothesis, or a choice of hypotheses, and I would explain them this way.

One hypothesis is that most of the time that we are interested in, when releases occurred, plumes were narrow and relatively little diluted. So the concentrations were very high, depositions were very localized and you have to face the consequences.

The other hypothesis would be that plumes were overwhelmingly or exclusively as wide as Mr. Woodard has computed them to be, right? They were so diluted already before they hit any hills or mountains that impaction could not occur, that these features had practically no influence on what happened at that — of course, you must also then draw the consequences from that.

And I am convinced out of my work that there is strong reasons for the hypothesis that plumes were most of the time were very narrow and undiluted, and I will explain that. Of course, the best proof of that would be either if we had seen these plumes or if we had been able to have detailed measurements up in the air, documenting these plumes. Right? . . . So we don't have that kind of information.

. . . . . .

> So I'm trying to obtain a picture of how such a hypothesis might be verified. And of course, it is also true that when I think of what I would have needed to really verify any hypothesis, some of these, many of these data are not, do not exist. For example, it would have been great to have many, many measurements of air concentration, because what the model, the Gaussian model, the first thing it gives you is concentration of the release, right? Of the substance. But there is no such measurement. There are some few measurements of iodine, but there is no measurement of the noble gases, as far as I remember, if I remember correctly, to until day eight or nine after the release, eight or nine days after the release, after the start of the accident.
>
> So this type of information is absolutely lacking. And I did look at, just to confirm some assumptions, some scenarios, I call them, I did look at concentration data. . . .

(Tr. at 618-21.) From this explanation, the court surmises that the Vergeiner hypothesis provides that a narrow and highly concentrated plume was emitted from TMI during the accident, and that the plume remained concentrated for a prolonged period of time. (Pls.' Findings of Fact and Conclusions of Law at 10 ("Dr. Vergeiner's hypothesis is that the plume from the TMI accident did not disperse in accordance with a Gaussian plume model, but instead remained in a concentrated form and travelled in a narrow plume manner.") (hereinafter "Pls.' Findings").) This

hypothesis is testable insofar as another expert could use the data employed by Dr. Vergeiner to reach an independent conclusion.[11] However, because Dr. Vergeiner elected to "eyeball" his plume movie drawings they would necessarily be difficult to accurately test or replicate. (See Vergeiner Dep. at 312-13.)

Additionally, Dr. Vergeiner's dose estimates do not lend themselves to empirical testing. The source terms used by Dr. Vergeiner as a basis for his estimates were provided by Plaintiffs' counsel.[12] Dr. Vergeiner himself could not explain how the figures were derived. Consequently, any expert

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11. Dr. Vergeiner has been roundly criticized by Defendants for his complete disregard of computer modeling, specifically the Gaussian Plume model, in connection with his plume dispersion analysis. Defendants have presented evidence that mathematical modeling, and the Gaussian model in particular, are accepted methods used within the relevant scientific field. (Tr. at 149.); see, e.g., The Rogovin Report (employing computer modeling to evaluate plume dispersion); The Kemeny Commission Report (same). Moreover, computer modeling is accepted and widely used by the Environmental Protection Agency and the Nuclear Regulatory Commission. See Cincinnati Gas & Elec. Co. v. Costle, 632 F.2d 14, 18-19 (6th Cir.1980) (discussing EPA's use of computer models to monitor air quality). Dr. Vergeiner, to the contrary, argues that a substantial body of evidence has developed within the relevant scientific community which supports the notion that the Gaussian model is inaccurate in a number of circumstances. (Tr. at 610-13.)

12. Plaintiffs have failed to come forward with any evidence tending to support the scientific validity of the terms which they supplied to Dr. Vergeiner. Presumably, the terms may have been based upon or related to Dr. Webb's source term estimates; however, the court has already found those estimates to be entirely unreliable.

endeavoring to test the validity of Dr. Vergeiner's dose estimates would be relegated to relying blindly on the source terms supplied by Plaintiffs' counsel. As such, it would be impossible to subject the dose hypothesis to rigorous and unbiased testing.[13]

Based upon the foregoing, the court finds that Dr. Vergeiner's hypothesis cannot be empirically tested. The bulk of Dr. Vergeiner's testimony consists of broad generalizations and suppositions regarding what might have happened during the accident. While such generalizations could provide a valid starting point for a detailed analysis, Dr. Vergeiner's opinions never move beyond this starting point. Thus, no hypothesis is advanced that is capable of being tested. Accordingly, this factor weighs against admitting Dr. Vergeiner's proffered testimony.

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13. In 1995, the National Research Council published a study entitled "Radiation Dose Reconstruction for Epidemiologic Uses." The purpose of the study was stated as follows: "to identif[y] criteria to be considered when undertaking radiation dose reconstructions studies, to examine the pitfalls encountered in previous studies, and to recommend areas of needed research." Committee on an Assessment of CDC Radiation Studies, Board on Radiation Effects Research, Commission on Life Sciences, National Research Counsel, "Radiation Dose Reconstruction for Epidemiologic Uses" at vii (National Academy Press 1995) (hereinafter "Radiation Dose Reconstruction"). Summarizing their findings with respect to full scale dose reconstruction studies, the Committee noted that "[d]ose reconstruction studies must rely on solid science, state-of-the-art methods, and careful peer review if they are to be viewed as credible. Ultimately, a dose reconstruction study will be judged by the scientific community primarily on the basis of the technical quality of the study and its contribution to science." Id. at 14.

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2. Has the Methodology Been Subject to Peer Review?

Insofar as boundary layer meteorology and synoptic analysis[14] are standard techniques, Dr. Vergeiner's use of

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14. During the hearings, Dr. Vergeiner gave the following explanation when asked by the court to explain "synoptic analysis":

> Synoptic meteorology is essentially the — comes out of the realization that when you plot weather observations taken at the same time, you know, which could be nighttime in Europe and late afternoon in this country, then you can draw maps. And you start to interpret them and you find out that, you will find certain prominent features, like weather fronts, and they would move in a coordinated way, right? You would get the rains first in, God knows where, in Chicago, and later on you would get them further east. And this is what's called synoptic meteorology.
>
> And to do that, of course, you don't want to look only at surface observations, but you do want to look at upper air observations, because the air moves faster at upper levels. And in order to interpret your features, you do want both surface and upper air observations.
>
> And for upper air, there is a network of balloons soundings, these big balloons with an instrument package, and they are launched every 12 hours at stations like Pittsburgh, New York — Albany, New York, Washington, D.C., stations at about that distance. And from those radio soundings, you get temperature and winds and pressure at upper levels. They are the backbone of synoptic meteorology.

(Tr. at 592-93.)

these standard techniques in a standard manner has been the subject of significant peer review. To the contrary, Dr. Vergeiner testified that the treatise that he prepared for this litigation has not been peer reviewed. (Tr. at 623.) However, Dr. Vergeiner stated that the principles underlying the conclusions reached in his treatise have been subject to peer review. (Id. at 624-26.) That Dr. Vergeiner has "been unable or unwilling to publish . . . [his] work undermines plaintiffs' claim that the findings [Dr. Vergeiner] proffer[s] are 'ground[ed] in the methods and procedures of science' and 'derived by scientific method.' " Daubert II, 43 F.3d at 1318 n. 9 (quoting Daubert, 509 U.S. at __, __, 113 S.Ct. at 2795, 2796). The court finds nothing to indicate that Dr. Vergeiner's plume movie or water model methodology has been subject to peer review.[15] Similarly, it is axiomatic that Dr. Vergeiner's methodology of adopting source terms presented to him by Plaintiffs' attorneys has not been subject to peer review.

This factor will weigh in favor of the admission of Dr. Vergeiner's basic meteorologic and synoptic analysis testimony, and against the admission of Dr. Vergeiner's plume movie, water model and dose estimate testimony.

3. Is There a Known or Potential Rate of Error?

During his testimony, Dr. Vergeiner did not discuss whether there existed any known or potential rate of error

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15. The important consideration here is not whether any models similar to those presented by Dr. Vergeiner have been peer reviewed, but whether the methodology he has employed in developing these models has been subject to peer review.

with respect to his methodology. Rather, he expounded upon his personal belief that "the general picture and the general magnitude of the concentrations of these plumes would be right," but that the exact course and concentration of the plume could not be calculated by anyone. (Tr. at 622-23.) The court finds the potential rate of error to be high. Much of Dr. Vergeiner's report, as mentioned above, is based upon speculation and estimates. Moreover, although Dr. Vergeiner stated that he believes that it is important to test a hypothesis, he did not thoroughly test his hypothesis. According to Dr. Vergeiner, he tested his hypothesis "to the limited extent that seemed sensible" to him. (Tr. at 663.) When asked to explain the limitations, Dr. Vergeiner noted that he "did not compare . . . [his] plume movie with TLDs because . . . [he] believe[d] that the TLDs have very bad instruments, very insensitive and very not useful for discriminating plumes." (Id. at 664.); cf. Whiting, 891 F.Supp. at 18 n. 24 (discussing the flawed methodology where expert disregarded primary and secondary data due to his unsubstantiated mistrust of the accuracy of TLDs). In qualifying this answer, Dr. Vergeiner concluded that "[w]e have to get away from the idea that anything that is called data or measurement is beyond criticism." (Id. at 664-65.)

In the long run, Dr. Vergeiner may be proven to be correct. TLDs[16] may eventually prove to be highly ineffective at measuring plume concentration. However, the court takes judicial notice of the fact that the relevant scientific communities regularly use TLDs and find them to be a valid means of measuring radioactivity. See NUREG-0637,

16. A "TLD" is a thermoluminescent dosimeter. These devices are used to measure airborne radiation.

"Report to the Nuclear Regulatory Commission from the Staff Panel on the Commission's Determination of an Extraordinary Nuclear Occurrence ("ENO")" at A1-A4 (January 1980) (general discussion of TLDs with specific attention paid to their use at TMI in conjunction with evaluating the TMI-2 accident). As such, the court finds that within the context of this litigation, Dr. Vergeiner's refusal to consider such information calls into question the reliability and scientific validity of his conclusions. At the very least, Dr. Vergeiner could have compared his results with the TLD readings and then explained to the court why his results were scientifically more sound than the TLDs. Instead, Dr. Vergeiner has disregarded arguably valid information without any rational explanation. The court finds that his failure to consider primary data in combination with his use of speculation, assumptions and "eyeballing" of figures, exposes Dr. Vergeiner's methodology to a potentially high rate of error. Moreover, the court finds that the failure of the water model to take into account the actual topography of the TMI area increases the risk that any demonstration run through the water model will be subject to a high rate of error. (10/18/95 Vergeiner Aff. at 6, ¶ 6 (discussing limitations of the water model).)

This factor will weigh against the admission of Dr. Vergeiner's testimony including his plume movie and water model.

4. Were There Standards Controlling the Technique's Operation?

The court finds this factor to have only tangential relevance to Dr. Vergeiner's proffered testimony. Insofar as

Dr. Vergeiner "eyeballed" his plume movie, the court holds that there were few standards controlling the operation of that technique. Further, the court finds that in making his dose estimates, Dr. Vergeiner failed to employ basic standards to control his technique's operation.[17] It appears that there were available standards to control the operation of the water model, see Water Model Report at 9; however, this will prove irrelevant in light of the other flaws which the court has already touched upon.

Based upon the foregoing, the court will not accord any weight to this factor when determining the admissibility of the proffered testimony.

5. Is the Methodology Generally Accepted?

Certain of Dr. Vergeiner's methodologies are generally accepted while others appear to be directly contrary to generally accepted methods. Dr. Vergeiner's methods with respect to his basic meteorological and synoptic analysis testimony are generally accepted. The parties do not dispute this. The plume dispersion and dose estimate methodologies

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17. Recognizing its merely average scientific acumen, and based upon its review of documents before it, the court believes that Dr. Vergeiner should have: (1) made some attempt to verify that the source terms provided to him by Plaintiffs' counsel were derived by a scientist with sufficient expertise using reliable and established methods; (2) run some of the more generally accepted computer models and tested his hypothesis against those models; (3) provided a detailed and scientific comparison between his model and the more accepted computer models and given specific scientifically based reasons why his model should be accepted as reliable.

cannot be categorized as generally accepted based upon a common flaw. At the hearing, Dr. Vergeiner testified that he discarded standard mathematical computer models[18] often used to estimate concentrations when actual concentration measurements are unavailable, see EPA 1992 at 22,912; NRC 1995 at 36, on the ground that the models did not take into consideration the complicated wind and topographical conditions at TMI. (Tr. at 562-66.) In his report, however, Dr. Vergeiner gives a less scientific explanation for his disregard of generally accepted methods:

> So why not straightaway model the flow numerically using the power of modern computers? Let me remind the reader of the enormous complexity of such a task. Transport and dispersion models exist to the hundreds, many of them in the nuclear industry or in the scientific "grey zone" around it. . . . Even to list the respective acronyms would fill pages.
>
> Quite a few of these models are global in scale, and some apparently have succeeded in simulating the path and contaminating action of the Chernobyl clouds reasonably well, after years of tuning and verification on the many observations available.

. . . . .

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18. "Computer dispersion modeling is the mathematical prediction of mixing different concentrations of gases in the atmosphere and the resulting effects in concentrations downwind under varying meteorological conditions." Tulou v. Raytheon Service Co., 659 A.2d 796, 799 (Del.Super.Ct.1995).

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> Documentation is a problem, as well as the need for special graphics and internal routines, or compatibility of various computer languages. Not all applications have been successes . . .
>
> It was my judgement, therefore, not only that it did not seem feasible to obtain access and results within a limited time span and financial frame, but that relatively simpler, well-tested, more robust and accessible models might be just as good, even preferable. This may appear to do injustice to the more than 50 man-years' [sic] expert work condensed in this enormous structure. There is no doubt that each of these models is capable of computing flow structures very suggestive of real nature, but I couldn't convince myself that the enormously increased expense would bear a sound relation to similarly improved results.

Ignaz Vergeiner, Treatise on the TMI-2 Accident of March 28, 1979, Particularly its Meteorological Aspects Including Transport and Dispersion of the Radionuclides Released, at 50 (July 1994) (hereinafter "Vergeiner Treatise I").

Dr. Vergeiner admits to discarding the generally accepted computer models with respect to his dose calculations and plume dispersion analysis. Moreover, he fails to provide the court with anything other than his bare assertion that the self-styled models he does employ are generally accepted. Dr. Vergeiner has not met his Daubert burden in this respect. Daubert II, 43 F.3d at 1319.

Based upon the foregoing, this factor will weigh in favor of excluding Dr. Vergeiner's testimony with respect to the plume movie and dose estimates. This factor will not weigh against the admission of the water model testimony.

6. Is There a Relationship Between the Technique and Methods That are Established to be Reliable?

Portions of Dr. Vergeiner's methodology resemble methods established to be reliable while other portions appear novel. Defendants do not challenge, and the court does not question, that Dr. Vergeiner's broad meteorological statements and synoptic analysis comport with established and reliable meteorological principles. Less can be said with respect to his plume movie, water model and dose estimates. Using computerized models, such as the Gaussian model, as the "established and reliable" method against which Dr. Vergeiner's methods must be judged,[19] the court finds no relationship between the two. Further, the court finds no recognizable similarities between established methods for dose reconstruction and Dr. Vergeiner's dose estimates. The literature does not support the notion that a scientist would blindly base a dose reconstruction upon an assumed and unverified source term supplied by attorneys. See, e.g., Radiation Dose Reconstruction at 16 ("A full description of the source term includes what was released and in what form and where and when the release occurred. These factors must be described with enough accuracy and detail both to satisfy

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19. The court has chosen to use computerized dispersion and mathematical models as the "established" technique because of their widespread use and acceptance. See supra, note 11.

the scientific requirements for the design and conduct of epidemiologic studies and to address the public's concern."); id. at 18 ("The credibility of a comprehensive source term study depends on confirming that all pertinent documents have been seen and evaluated. Complete records are essential in identifying the source term.")

The court finds that this factor weighs in favor of excluding Dr. Vergeiner's plume movie, water model and dose estimate testimony.

7. Qualifications of the Expert Based Upon the Methodology

Dr. Vergeiner's curriculum vitae evidences his qualifications as a meteorological expert. Moreover, Defendants do not challenge his credentials. The court, however, questions Dr. Vergeiner's ability to opine as an expert with respect to his dose estimates. A review of his curriculum vitae reveals no specialized experience tending to qualify Dr. Vergeiner as an expert in the area of dose reconstruction.[20] Thus, while the court agrees with Plaintiffs that "Dr. Vergeiner's meteorological credentials unquestionably qualify him for his analysis of weather-related plume dispersion", the court disagrees that this experience also qualifies him to discuss dose estimates. (Pls.' Brief in Opposition at 74.)

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20. The court also notes that it finds Dr. Vergeiner's testimony regarding his qualifications in this area to demonstrate his lack of expertise. (Tr. at 561.)

Based upon the foregoing the court finds that this factor weighs against the admission of Dr. Vergeiner's dose estimate testimony. It weighs in favor of his meteorological and synoptic analysis testimony, and will not weigh against the admission of the plume movie and water model.

8. Non-Judicial Uses of the Methodology

Insofar as Dr. Vergeiner's methods reflect standard meteorological analysis, they are widely used in non-judicial settings. The methodology followed with respect to the plume movie, water model and dose estimates deviates from standard methodology and appears to have been derived solely in connection with this litigation. This factor will weigh against the admission of Dr. Vergeiner's plume movie, water model and dose estimate testimony.

9. Other Factors

In conjunction with the above Daubert/Paoli II analysis, the court indicated that Dr. Vergeiner's explanations are, by and large, not subject to falsification. Further, while his hypothesis is generally logically consistent, it is not consistent with accepted theories. Most striking is Dr. Vergeiner's disregard of primary data. While Dr. Vergeiner might prove to be ahead of his time in his disdain for TLDs, TLDs are currently accepted devices for measuring atmospheric radiation. As such, Dr. Vergeiner's cursory disregard of such measurements is unacceptable. Finally, the court finds that Dr. Vergeiner's plume movie and water model lack precision. "[B]road generalization[s] that can account for any possible state of affairs . . . cannot be

empirically tested, [and thus] are not as good." Science 72 Tex.L.Rev. at 784. Dr. Vergeiner himself indicated that his models are nothing more than generalizations and suppositions about what might have happened during the TMI accident. (Tr. at 635-36; Vergeiner Dep. at 278-79.) As such, the models are necessarily imprecise.

C. Rule 702 Fit

The court's analysis of the Daubert/Paoli II factors militates in favor of excluding Dr. Vergeiner's plume movie and water model. While the court could exclude the proffered testimony based solely on those grounds, the court finds the more appropriate ground for exclusion of the plume movie and water model to be an absence of "fit." The plume movie and water model are not accurate depictions of plume dispersion during the TMI accident. Plaintiffs do not dispute this fact. These models, instead, are proffered to demonstrate what may have happened. The models might have "fit" within the case if they bore any meaningful relationship to the actual topography of the TMI area or to the primary data.

The plume movie does not "fit" within the case because it is based upon an undefined source term, fails to account for weather readings on the TMI weather tower, and fails to incorporate all primary data. Thus, it cannot be found to bear a valid relationship to the TMI accident. Similarly, the water model does not take into account the actual topography of the TMI area. Any demonstration performed using the water model, therefore, would not bear a close relationship to the way a substance would be dispersed into the atmosphere around TMI. "Federal judges must . . . exclude proffered

scientific evidence under Rules 702 and 403 unless they are convinced that it speaks clearly and directly to an issue in dispute in the case, and that it will not mislead the jury." Daubert II, 43 F.3d at 1311 n. 17. Neither the plume movie nor the water model speak clearly to any issue in dispute in this case.[21] Because neither purports to provide an accurate representation of plume dispersion during the accident, the models cannot "clearly" speak to anything. Furthermore, there is a high potential that such models would mislead a jury insofar as the jury might perceive the models to accurately represent the manner in which plumes did disperse during the accident. The court will exclude the plume movie and water model testimony pursuant to Rules 702 and 403. Robinson v. Missouri Pacific R.R. Co., 16 F.3d 1083, 1089 (10th Cir.1994) ("Concerning future similar issues under Rule 702 we suggest that as 'gatekeeper' the district court carefully and meticulously make an early pretrial evaluation of issues of admissibility, particularly of scientific expert opinions in films or animations illustrative of such opinions.").

D. Conclusion

The foregoing analysis reveals that a significant portion of Dr. Vergeiner's proffered testimony is unreliable and therefore inadmissible pursuant to Rule 702. Specifically, Dr. Vergeiner's dose estimates will be excluded at trial as lacking scientific validity and reliability. Further, the court will exclude Dr. Vergeiner's plume movie and water model

21. Additionally, Dr. Vergeiner has stated that he did not use the water model in performing his dose reconstruction. (Vergeiner Dep. at 30, 204-05, 323-27.)

as lacking the necessary "fit" with the instant litigation pursuant to Rule 702, and as potentially confusing to the jury pursuant to Rule 403. McKnight v. Johnson Controls, Inc., 36 F.3d 1396, 1402 (8th Cir.1994) (excluding simulation "where some principles of some kind may be demonstrated but in a fashion that looks very much like a recreation of the events that gave rise to the trial"); Robinson, 16 F.3d at 1089 n. 7 (noting that Rule 403 prejudice is a ground that a court should consider for exclusion of computer simulations and animations and the like); Fusco v. General Motors Corp., 11 F.3d 259, 264 (1st Cir.1993) (excluding accident replication videotape where the drama of the videotape was capable of overcoming the logic of the distinctions raised by opposing experts). As Dr. Vergeiner is an expert in meteorology, and can offer insights regarding the weather conditions during and immediately following the accident, the court will not exclude his testimony in this narrow area. The court will, however, require Plaintiffs to give a proffer as to how this narrow area of testimony "fits" absent Dr. Vergeiner's other proposed testimony. (See Defs.' Findings at 54, ¶ 8 (challenging the "fit" of the synoptic analysis presuming the inadmissibility of the plume movie and dose estimates).)

VI. CHARLES E. ARMENTROUT

Professor Armentrout has masters degrees in Physics and Radiological Physics. According to his curriculum vitae, he is currently an Associate Professor at the University of Southern Maine. Professor Armentrout's proffered testimony can be divided into four distinct areas as follows: (1) a discussion of what Armentrout calls "anomalously high"

radiation background readings measured in Portland, Maine a few days after the TMI accident (2/20/95 Armentrout Rpt. at 2-4); (2) the results of soil sample analyses performed by Victor Neuwirth on soil samples extracted from TMI and its surrounding areas (id. at 4-23); (3) a discussion of radiation survey meter readings allegedly taken by a local resident during the TMI accident; and, (4) an explanation of the rate-dependant behavior of Geiger-Muller radiation detectors. (Id. at 26.)[22] The court has already precluded Professor Armentrout from testifying as to the substance of Victor Neuwirth's report (e.g. soil sampling techniques and results). In re TMI, No. 88-1452 (M.D.Pa. November 9, 1995) (preliminary order ruling on portions of Defendants' motion in limine). Professor Neuwirth filed his own report and testified at the in limine hearings. Accordingly, Plaintiffs' proffer with respect to the Armentrout/Neuwirth soil sample analysis will be evaluated pursuant to the court's discussion of the Neuwirth proffer. The court will now evaluate the remaining areas of Professor Armentrout's proffered testimony.

A. Proffered Testimony

1. Section I of the Armentrout Report

On March 31, 1979, following a discussion with a former student, Professor Armentrout and that student assembled radiation detection equipment on the roof of the science building at the University of Southern Maine. (2/20/95 Armentrout Rpt. at 3.) The equipment recorded two "bursts"

22. Because neither Plaintiffs nor Defendants have addressed this testimony, the court will not rule at this time.

of what Professor Armentrout identifies as anomalous radiation readings. (Tr. at 1248-49.) Professor Armentrout memorialized his observations in a letter to the President of the University of Southern Maine. (Tr. at 1252-53.) The letter has been made part of the record. (2/20/95 Armentrout Rpt., Ex. A.) In his report, Professor Armentrout claims that government installations around Portland, Maine recorded similar radiation readings during the same time frame as his readings. (2/20/95 Armentrout Rpt. at 4.) Further, he notes that a Science magazine article stated that unusual radiation measurements were taken in Albany, New York shortly after the accident. Professor Armentrout contends that these reports verify the readings that he recorded and indicate that the TMI plume passed over the area. (2/20/95 Armentrout Rpt. at 4 & n. 4.) Despite these alleged "verifications," Professor Armentrout testified that his readings do not tell him with a reasonable degree of scientific certainty what radionuclides were released at TMI or how large the release was. (Tr. at 1290.)

Defendants contend that this portion of Professor Armentrout's proffered testimony should be excluded as it will not be helpful to the trier of fact. (Defs.' Findings at 81, ¶ 15.) Plaintiffs' findings do not directly address this section of the Armentrout report, but rather, focus on the soil sampling techniques and results. The court agrees with Defendants insofar as the testimony does not "fit" with any material fact in issue. Equipment on the roof of the science building at the University of Southern Maine registered radiation "spikes" shortly after the TMI accident began. Professor Armentrout suggests that the readings support the theory that the TMI plume passed over Maine. This

contention is made absent reliable scientific corroboration or verification, and thus, cannot tie the radiation readings to any occurrence at TMI. Accordingly, the court finds that the proffered testimony will not assist the jury in determining any fact in issue. Professor Armentrout will be precluded from testifying as to the substance of section I of his report.[23]

2. Section III of the Armentrout Report

In this section, Professor Armentrout speaks to his attempts to verify alleged radiation readings taken by civilians living near TMI during the accident. After repeated phone contact from a resident of Etters, Pennsylvania,[24] Professor Armentrout attempted to verify the resident's alleged radiation readings. Professor Armentrout devised a means to calibrate the resident's ion chamber monitor, and came to the Harrisburg area to meet with the gentleman and verify the alleged readings. However, when Professor Armentrout arrived in the area, he could not locate the gentleman who had contacted him. Instead, Professor

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23. Because the proffered testimony is so obviously lacking in scientific basis, the court will not take the time to trudge through the Daubert/Paoli II analysis. The Daubert/Paoli II factors are geared toward analyzing scientific testimony. As such, they presume a certain level expertise with respect to the organization and structure of a study. Studies wholly lacking in scientific basis are not organized or relayed to the court in a format similar to traditional scientific studies. Thus, they do not lend themselves to application of the Daubert/Paoli II analysis.

24. No identifying names are used in the following discussion because the court has not been provided with the names of either the Etters resident or his neighbor.

Armentrout spoke to a neighbor who remembered the that he and the missing gentleman had purchased identical ion chamber monitors[25] from a local store. Further, this neighbor remembered that he made an indoor reading during the accident that sent his monitor off-scale. (Armentrout Rpt. at 25.) Professor Armentrout contends that this incident verifies the first gentleman's reports of the high readings that he took during the accident.

Defendants challenge this section of the report "because experts in the field of dose reconstruction would not rely on hearsay statements which even Armentrout admitted were unreliable." (Defs.' Findings at 81, ¶ 16.) Again, Plaintiffs do not directly address this section of the Armentrout report, instead electing to concentrate on the soil sample analysis. The court must agree with Defendants. This anecdotal evidence does not meet the most basic standards of scientific validity or reliability. Accordingly, the court will exclude the testimony proffered in section III of the Armentrout report.

3. Conclusion

Based upon the foregoing, the court finds the testimony proffered in section I of the Armentrout report to lack scientific validity, reliability and the requisite "fit" with the

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25. "[I]on chamber monitors . . . [have been] used at the government's Nevada test site and elsewhere for measuring the levels of ion radiation fluxes, commonly referred to as background radiation." Dept. of Energy v. White, 653 F.2d 479, 481 (Cust. & Pat.App.1981), cert. denied, 454 U.S. 1144, 102 S.Ct. 1005, 71 L.Ed.2d 296 (1982).

instant litigation. The testimony proffered in section III similarly lacks scientific validity and reliability; therefore, the testimony will be excluded. The court will now turn to the Neuwirth proffer and determine whether the testimony will be admitted at trial. Evaluation of the Neuwirth proffer will necessarily involve discussion of that portion of section II of the Armentrout report authored by Professor Armentrout.

VII. VICTOR J. NEUWIRTH

Victor Neuwirth is a laboratory associate and Professor of Chemistry at the University of Southern Maine. Professor Armentrout enlisted the support of Professor Neuwirth to analyze soil samples from the TMI area to determine whether he could extract potentially radioactive materials from the samples. Professor Neuwirth performed the analysis on the soil samples and authored the portion of the Armentrout report dealing with the soil sample analysis. Additionally, Professor Neuwirth testified during the in limine hearings. Defendants challenge the proffered testimony as lacking a Rule 702 "fit" because no connection can be made between the results of the soil sampling and the 1979 TMI accident. (See Defs.' Findings at 87, ¶ 1.)

A. The Proffered Testimony

If permitted, Professor Neuwirth will testify as to the methods he employed and the results he obtained in analyzing certain TMI soil samples. At the direction of Professor Armentrout, Professor Neuwirth concentrated soil samples provided to him by Professor Armentrout and used a sodium

iodine detector to make integrated counts of radionuclides.[26] (Tr. at 1065-66; Armentrout Rpt. at 7-9.) Professor Neuwirth found certain samples to contain radioactive materials, but was unable to identify specific radionuclides. Despite his inability to identify specific radionuclides, Professor Armentrout directed him to calculate the half life of each of the soil samples as a whole (rather than calculating the half lives of specific radionuclides within each soil sample).[27] Professor Neuwirth took measurements of the same soil samples at a one year interval, with no intermediate readings. Based upon these two data points, he made a generalized half life calculation for each of the samples. Professor Armentrout used Professor Neuwirth's half life calculations to make dose estimates for the TMI Plaintiffs.

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26. A "radionuclide" is an unstable nuclide that can undergo radioactive decay. (1/20/93 Aff. of Dr. John Fraizer at ¶ 9.)

27. It is the court's understanding that a variety of radionuclides, with a corresponding variety of half lives, can be found in any soil sample. Thus, it is more accurate to isolate each radionuclide and calculate a half life for that radionuclide, than it is to measure the overall radioactivity of the entire sample and derive a generalized or average half life for the entire sample. See Allen v. United States, 588 F.Supp. 247, 276 (D.Utah 1984) ("Measurement in curies does not, however, define the type or energy of the radiation being emitted. That information is specific to each radionuclide and is important to the evaluation of the risk created by exposure to curie, millicurie, or microcurie in amounts of material."), rev'd on other grounds, 816 F.2d 1417 (10th Cir.1987), cert. denied, 484 U.S. 1004, 108 S.Ct. 694, 98 L.Ed.2d 647 (1988).

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B. Daubert/Paoli Analysis

1. Does the Method Consist of a Testable Hypothesis?

Plaintiffs contend that Professor Neuwirth's hypothesis may be tested. Defendants do not directly address this issue. Professor Neuwirth's hypothesis is that radioactive decay observed in the TMI soil samples is attributable to TMI fission products.[28] Plaintiffs argue that this hypothesis may be falsified insofar as the chemical extraction process would either prove or disprove the notion that the soil samples were radioactive. The court agrees that this portion of the hypothesis is testable, and that it has been tested. However, the effect of the testing was negated as Professor Neuwirth did not use the test results to modify his hypothesis. After completing his soil sample analysis, Professor Neuwirth sent the samples to the Data Chem laboratories to obtain more specific radionuclide readings. The Data Chem results falsify Professor Neuwirth's hypothesis in that they demonstrate that the samples contain little other than naturally occurring background levels of radiation.[29] (Tr. at 295-303, 1050-52, 1296, 1298, 1300, 1303.) A proper methodology would have

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28. "Fission products" are "the nuclear fragments resulting from the splitting of uranium or plutonium nuclei." Allen, 588 F.Supp. at 288.

29. "Natural background radiation" is radiation arising from radiation sources that occur naturally in the environment. See 10 C.F.R. § 20.1003 (1995). "Natural radioactivity is all around us, in soil, in building materials, and in trace amounts in meat, vegetables, fruits, grains and drinking water." Allen, 588 F.Supp. at 327.

incorporated these findings and appropriately modified the underlying hypothesis. Professor Neuwirth neither acknowledged the findings nor modified the initial hypothesis.

Of more concern to the court are Professor Neuwirth's half life calculations. Because he was unable to identify specific radionuclides within any sample, Professor Neuwirth was forced to make a generalized half life estimate for each soil sample as a whole. The estimate was based upon taking two separate readings of each sample with one year separating the two readings. Based upon the decay in the sample over an entire year, half life values were calculated. Professor Armentrout then used the Neuwirth half life values to derive dose estimates for TMI residents.

Based upon the foregoing, this factor will weigh against the admission of the soil sample and half life calculation testimony.

2. Has the Methodology Been Subject to Peer Review?

The parties do not dispute that the chemical extraction process employed by Professor Neuwirth has been subject to peer review. It is doubtful, however, that the half life calculation technique utilized by Professor Neuwirth has been subject to peer review. Defense expert Dade Moeller testified that to determine the half life of a material, measurements must be taken at periodic intervals over time. (Tr. at 293-94.) He further testified that it is important to have more than two data points from which to calculate the

half life. (Id.) Plaintiffs provide no evidence that the half life calculation approach utilized by Professor Neuwirth on the TMI soil samples has been peer reviewed. Consequently, the court finds that this factor weighs in favor of the admission of the chemical extraction testimony and against the admission of the half life calculation testimony.

3. Is There a Known or Potential Rate of Error?

Professor Neuwirth testified to the rate of error for his soil extraction calculations. (Tr. at 1033.) Based upon the testimony, the court believes that this is a standard rate of error for what the court has already found to be a standard extraction procedure. This factor will not weigh against the admission of the extraction testimony. To the contrary, the court finds the potential rate of error with respect to the half life calculations and dose estimates to be high. As discussed above, Professor Neuwirth used only two data points when making his half life estimates. Consequently, the calculation does not accurately categorize the decay rate of the sample. See Allen v. United States, 588 F.Supp. 247, 276 (D.Utah 1984); (Tr. at 293- 94.). Because the decay rate is not properly categorized, the potential rate of error in estimating the half life value is high. Moreover, any error in the half life calculation carries over into Professor Armentrout's dose estimates as the half life calculations were integral to the dose calculations. Thus, this factor will weigh against the admission of the half life calculation and dose estimate testimony.

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4. Were There Standards Controlling the Techniques Operation?

"A well-designed experiment shows how one variable responds to changes in variables under the control of the experimenter." Federal Judicial Center, Reference Manual on Scientific Evidence 347 (1994) (hereinafter "Reference Manual"). The court believes that the Neuwirth soil analysis can be categorized as an observational study. The Reference Manual notes the following regarding observational studies:

> In an experiment the investigators select certain units for treatment. In an observational study the investigators have no control over who or what receives the treatment.
>
> . . . . .
>
> In such observational studies, investigators may speak of control groups . . . and of controlling for potentially confounding variables . . . [h]owever . . . the causal inferences that can be drawn from such analyses rest on a less secure foundation than that provided by a controlled randomized experiment.

Research Manual at 351. During the hearings, Professor Neuwirth acknowledged that he and Professor Armentrout had yet to obtain a suitable control group from the TMI area. This control group, when found, would be used to confirm test results and assure that their equipment was functioning properly. (Tr. at 1022-23.) Professor Neuwirth also indicated

that he never compared his samples with soil samples taken at or near the time of the TMI accident to determine whether his data was accurate or whether Professor Armentrout's half life assumption was correct. (Tr. at 1045-46.) Professors Neuwirth and Armentrout have started with a less reliable methodology, and by their failure to find a suitable control group, placed the question of reliability into greater doubt. This factor will weigh against the admission of the proffered testimony.

5. Is the Methodology Generally Accepted?

Although Defendants argue that use of gamma spectrometry, rather than use of a sodium iodine detector, is the preferable means of identifying specific radionuclides, Defendants do not suggest that sodium iodine detectors are not generally accepted. (Defs.' Findings at 70, ¶ 8.) Indeed, Professor Neuwirth testified that his soil extraction techniques are generally accepted standard techniques. (Tr. at 1024-25.) The court finds that the technique utilized by Professor Neuwirth is generally accepted, and that the issue of whether it is the preferred technique goes to weight rather than admissibility. This factor will not weigh against the admission of the soil sample testimony.

The half life calculation methodology employed by Professor Armentrout does not enjoy the same level of acceptance as Professor Neuwirth's extraction methods. There is nothing before the court to indicate that it is generally accepted to make a broad half life calculation of a sample in lieu of delineating specific radionuclides within the sample and assigning half life values to each radionuclide.

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An expert's self-serving assertion that his methodology is standard of generally accepted will not withstand the rigors of a Daubert/Paoli II analysis. Daubert II, 43 F.3d at 1319 ("[P]laintiffs rely entirely on the experts' unadorned assertions that the methodology they employed comports with standard scientific procedures. . . . We've been presented with only the experts' qualifications, their conclusions and their assurances of reliability. Under Daubert that's not enough.") Accordingly, this factor will weigh against the admission of Professor Armentrout's half life calculation testimony.

6. Is There a Relationship Between the Technique and Methods That are Established to be Reliable?

The court finds this factor most applicable to Professor Armentrout's half life calculations. Dr. Moeller testified as to the proper and established techniques for calculating half lives of radionuclides.[30] Specifically, Dr. Moeller noted as follows:

> In order to determine the half-life of a radioactive material, you must count it at periodic intervals, counting it over, you know, a period of time, and certainly you have a number of points, and then you plot those points on a curve. And if you plot the points on semi-log paper where the activity is on a logarithmic scale and the time is on an

30. The court credits Dr. Moeller's testimony based upon its consistency with accepted scientific principles. See Allen, 588 F.Supp. at 276.

> arithmetic scale, the points will follow a straight line if, indeed, you have one radionuclide and you're following its half-life and the half-life is short enough so that it has decayed over the time period in which you're counting it. He used his first and his last points and drew a straight line between them, and although he had at least in one case, an intermediate point, he did not bother to plot it. It would not have plotted on the straight line. And on the basis of that, and assuming that he had one radionuclide, he estimated a half-life.

(Tr. at 293.) Professor Armentrout's methodology bears little relation to the established and reliable methodology outlined above by Dr. Moeller. The court finds that this factor weighs against the admission of Professor Armentrout's half life calculations.

Similarly, Professor Neuwirth's soil extraction techniques lack a key component evident in accepted and reliable methodologies — a suitable control sample. Without an appropriate control sample, it is impossible for Professors Armentrout and Neuwirth to verify their results in any meaningful way. This factor weighs against the admission of the soil sample analysis testimony.

7. Qualifications of the Expert Based Upon the Methodology

Defendants do not challenge the qualifications of either Professor Neuwirth or Professor Armentrout. As the court agrees that Professor Neuwirth is qualified to testify as to

the soil sample analysis and that Professor Armentrout is qualified to testify as to his half life calculations, no further evaluation of this factor is necessary. This factor will not weigh against the admission of the proffered testimony.

8. Non-Judicial Uses of the Methodology

In a general sense, sodium iodine detectors are utilized and half life calculations are made in a variety of non-judicial settings. Indeed, but for the unique nature of this case, it is questionable whether these types of methodologies would ever have judicial uses. This factor will not weigh against the admission of the proffered testimony.

C. Conclusion

Based upon the foregoing analysis, the court will exclude Professor Armentrout's testimony on half life calculations and Professor Neuwirth's testimony regarding his soil sample analysis. The testimony is not "derived from scientific method", and does not represent "good science." Daubert, 509 U.S. at __, __, 113 S.Ct. at 2795, 2797.

VIII. JAMES E. GUNCKEL

Dr. Gunckel is a Ph.D. biologist now retired from a long-time position at Rutgers University, where he specialized in studying the effects of radiation on plants. A significant portion of Dr. Gunckel's work experience involves his collaborative studies with Dr. Sparrow and the Brookhaven National Laboratory regarding the effect of radiation on plants. Dr. Gunckel is not a health physicist, nor does he have expertise in the area of tree biology.

Appendix G

A. Proffered Testimony

Dr. Gunckel's report consists of his evaluation of damaged trees in the TMI area, study of human and animal health in the TMI area, and estimates of dose based upon the tree, human and animal studies. The Gunckel hypothesis is as follows:

> Radiation induced growth effects in trees would occur in areas where residents experienced symptoms indicating exposures to radioactivity at the time of the TMI accident and that those tree effects would occur in several species showing relative sensitivities (slight and severe growth effects, and lethality) corresponding to those determined in Brookhaven.

(10/23/95 Gunckel Aff. at 12.) Based upon his interviews with humans who complained of health irregularities during and after the accident, Dr. Gunckel concluded that a dose of 300-360 rem[31] was "the top dose at TMI that we could recognize by our yardsticks." (Tr. at 1606.) This 360 rem dose is equal to "LD-50/60" — the dose at which "50 percent of the population would die from that dose in 60 days." (Tr. at 1608.) Further, Dr. Gunckel indicated that he chose to study damaged trees located in the same areas as humans with health complaints to establish a method of comparing

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31. The unit of dose equivalent, "rem," is equal to 0.01 joule per kilogram in man. The dose equivalent in rems is equivalent to the absorbed dose in rads multiplied by the quality factor. 10 C.F.R. § 20.1004 (1995). A "rad" is the unit of absorbed dose equal to 0.01 joule per kilogram in any medium, 0.01 gray. Id.

the erythema doses[32] experienced by humans with the doses presumably experienced by the trees. (Id. at 1606-07.) Through his study, Dr. Gunckel has concluded that the dose to trees was in the area of 1000 rem. (5/13/93 Rpt. at 10.) Dr. Gunckel is unable to adequately explain how doses of 360 rems to humans and 1000 rems to trees were delivered without significant human casualties. (See Tr. at 1611.)

The court will now evaluate Dr. Gunckel's proffered testimony in light of the Daubert/Paoli II factors. The trees studies will be viewed separately from the human and animal studies. Additional facts related to each of these areas will be set forth where the court determines such explanation is necessary or helpful.

B. Daubert/Paoli II Analysis

1. Does the Method Consist of a Testable Hypothesis?

Dr. Gunckel has advanced a hypothesis capable of falsification. However, no effort has been made to verify either methodology or the conclusions reached.

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32. "Erythema" is defined as "redness of the skin produced by congestion of the capillaries, which may result from a variety of causes, the etiology or a specific type of lesion often being indicated by a modifying term." Dorland's Illustrated Medical Dictionary at 577 (27th ed. 1988). Here, it is posited that the erythema resulted from radiation exposure.

Appendix G

a. Study of Human and Animal Health

In connection with this study, Dr. Gunckel interviewed approximately fifteen TMI residents regarding health effects they reportedly experienced at the time of the TMI accident. (Tr. at 1600-02.) During direct examination at the hearing, Dr. Gunckel described the nature and execution of his human health study as follows:

> We went to these sites, and this was the case of revisiting the sites where people had complained of some sort of health effect. So we were there to do two things: First, to talk with them and to reaffirm whether their alleged effects were real, possible, or not, not trying to say as a doctor would be qualified to say that they had suffered from this, that and the other thing. We were simply asking, sort of trying to get a composite view of what had gone on. So we were not passing on identifying whether what they complained of was true or false. We were simply trying to associate people with possible episodic evidence with a plant indicator. That is, if we could — well, the ideal thing, of course, is if we had one of these indicators on every site and we could look at the indicator and see what the indication of damage was, and then going to our Brookhaven data bank, we could translate that effect into a dose. [Further we] . . . found people weren't very well informed, frankly, about what had happened to them. So you really had to go armed with a list of possibilities and see if they could recall or whether they had

> had anything on their medical records to authenticate what they thought they had experienced. . . . Specifically, we had a lot of conditions like, oh, let me see. Nausea, vomiting . . . petechiae. . . . low white blood counts. . . . abnormal tastes and smells at the time.

(Tr. at 1600-01.) Based upon his interviews,[33] Dr. Gunckel concluded that five of the fifteen study subjects were exposed to erythemic doses.

In theory, Dr. Gunckel's methodology is testable. He could have examined the medical records of the study subjects to determine whether their health complaints were consistent with a pre-existing medical condition.[34] Further,

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33. Dr. Gunckel described the interview process as follows:

> We went to these sites, and this was the case of revisiting the sites where people had complained of some sort of health effect. So we were there to do two things: First, to talk with them and to reaffirm whether their alleged effects were real, possible, or not, not trying to say as a doctor would be qualified to say that they had suffered from this, that and the other thing. We were simply asking, sort of trying to get a composite view of what had gone on. So we were not passing on identifying whether what they complained of was true or false. We were simply trying to associate people with possible episodic evidence with a plant indicator.

(Tr. at 1600.)

34. In his deposition, Dr. Gunckel admitted that some of the information which he relied upon was not contained within the (Cont'd)

Dr. Gunckel could have made a differential diagnosis of each study subject to rule out potential causes of their symptoms other than radiation.[35] Most important for this court's purposes, however, is that Dr. Gunckel made no effort to falsify and then modify his hypothesis. This factor will weigh against the admission of the proffered human/animal study testimony.

b. The Tree Study

After identifying areas in which persons described health effects allegedly related to the TMI accident, Dr. Gunckel looked for tree damage in these identified areas. At the hearing, Dr. Gunckel testified that he selected 80 damaged trees located in the fifteen areas where there was anecdotal evidence of human and animal health effects. (Tr. at 1608, 1610.) In describing how he selected the trees for his study, Dr. Gunckel noted the following:

(Cont'd)
subject's medical records. See, e.g., Gunckel Dep. at 173 ("[The doctor] said it couldn't be erythema because, because Met Ed and NRC said that no, no radiation got out. So he did not put it in her medical record that she had received an erythema dose. . . ." "Q. So you're reporting what she reported her doctor said?" "A. That's right.").

35. At this point Dr. Gunckel's qualifications would come into play. As will be discussed infra, Dr. Gunckel is not qualified to review medical records, form an opinion, and opine as a medical expert. (See Gunckel Dep. at 16, 169.) Therefore, even if this would have been the correct direction for his research to take, it is likely that Dr. Gunckel would have needed to employ someone with greater medical expertise to conduct this portion of his study.

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> [T]he kind of test I used, a very vague one, is the rule of thumb that most every observer uses on this sort of thing. If the tree, if the crown of the tree showed signs of thinning, in other words, you can see it better on a deciduous tree than you can on a pine tree, showed signs of thinning, in other words, it's losing its leaves, that's the first thing that comes down. And then if beyond that, you found that you had a color change, a color change is very significant in indicating that the tree is not terribly happy.
>
> . . . . . .
>
> And I'll certify every one of those trees as having received a thousand roentgen dose, which was adequate to kill the tip of the plant, the leader, the apical meristem of the leader on the tree.

(Tr. at 1608-09.) Notably, Dr. Gunckel did not attempt any type of differential diagnosis with the trees to determine whether their injury could have been caused by something other than radiation. (Gunckel Dep. at 188.) Thus, the court is again presented with a hypothesis that could be tested but that has not been tested. This factor will weigh against the admission of the proffered tree study testimony.

Appendix G

2. Has the Methodology Been Subject to Peer Review?

a. Study of Human and Animal Health

Nothing before the court indicates that the human and animal health study methodology has been subject to peer review.

> Peer review and publication do not, of course, guarantee that the conclusions reached are correct; much published scientific research is greeted with intense skepticism and is not borne out by further research. But the test under Daubert is not the correctness of the expert's conclusions but the soundness of his methodology. That the research is accepted for publication in a reputable scientific journal after being subjected to the usual rigors of peer review is a significant indication that it is taken seriously by other scientists, i.e., that it meets at least the minimal criteria of good science.

Daubert II, 43 F.3d at 1318. It is most curious to the court that in the sixteen years that this litigation has been pending, none of Plaintiffs' experts' reports, including this one, have been submitted for publication. This type of report, one purporting to show that persons and animals in the TMI area during the accident received erythemic doses, would surely be of interest to the relevant scientific community and the public at large. Yet, as Judge Kozinski of the Ninth Circuit observed of the Bendectin cases, "[i]t's as if there were a tacit understanding within the scientific community that

what's going on here is not science at all, but litigation." Id. (footnote omitted). This factor will weigh against the admission of the human and animal study.

b. The Tree Study

Plaintiffs contend that all methodologies utilized in the tree study have been the subject of extensive peer review. This argument is based on Plaintiffs' characterization of the TMI tree study as being similar to studies performed by Dr. Gunckel and the late Dr. Sparrow at the Brookhaven National Laboratory. The court cannot agree with Plaintiffs' characterization insofar as the TMI tree studies bear no functional relevance to the Brookhaven studies.[36] At Brookhaven, Drs. Gunckel and Sparrow irradiated trees with known doses of radiation using a gamma field. They then observed the effects exhibited by the trees following the known exposure. Finally, the doctors created a data base of the observations made and based upon the known dose exposures. To the contrary, the instant study involved looking at damaged trees and using the Brookhaven database to infer maximum possible dosage.[37] Accordingly, the fact that the

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36. A key component of the studies performed by Drs. Gunckel and Sparrow at Brookhaven were cellular and subcellular studies on the trees. They used these cellular and subcellular evaluations to determine the extent of damage done to the trees by radiation. These studies did not include viewing morphological damage to trees. (See Tr. at 1595, 1618.)

37. Defendants have raised an issue as to whether the Brookhaven studies ever involved mature trees. (Defs.' Findings at 94, ¶ 21.)

initial Brookhaven studies were subject to extensive peer review is of little relevance to the study presently before the court.

As with the human and animal study, the court finds it odd that Dr. Gunckel's tree study has never been submitted for publication. This factor will weigh against the admission of the proffered tree study testimony.

3. Is There a Known or Potential Rate of Error?

a. Study of Human and Animal Health

Dr. Gunckel does not assign any specific rate of error to his human and animal health study. The court, however, finds the potential rate of error to be high. According to Dr. Gunckel's in limine testimony, his opinion on dose at TMI is based primarily on the erythema allegedly experienced by five individuals he interviewed.[38] Dr. Gunckel did not review

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38. Speaking to the issue of medical reports prepared for litigation, the Third Circuit has stated:

> We do not doubt the propriety of a medical report prepared just for litigation purposes, but a physician who evaluates a patient in preparation for litigation should seek more than a patient's self-report of symptoms or illness and hence should either examine the patient or review the patient's medical records simply in order to determine that a patient is ill and what illness the patient has contracted.

. . . . . .

(Cont'd)

medical records or perform differential diagnosis. Moreover, as the court will discuss infra, Dr. Gunckel does not have the expertise in human or animal medicine sufficient to draw conclusions regarding medical conditions. Dana Corp. v. American Standard Inc., 866 F.Supp. 1481, 1501 (N.D.Ind. 1994) ("An expert's opinion 'must be an "expert" opinion (that is, an opinion informed by the witness's expertise) rather than simply an opinion broached by a purported expert.' " (citing United States v. Benson, 941 F.2d 598, 604 (7th Cir.1991)). Finally, Dr. Gunckel did not employ any type of systematic survey, or case-control comparison of the TMI residents. (See Tr. at 1600.) These flaws in the methodology evidence to the court a potentially high rate of error. This factor will weigh against the admission of the human and animal health study testimony.

b. The Tree Study

During his in limine testimony, Dr. Gunckel proclaimed the rate of error with respect to his tree study to be five percent (5%). (Tr. at 1623.) It is not entirely clear how Dr. Gunckel calculated this rate of error, but his explanation indicates that this is the rate of error assigned to the work conducted by Dr. Gunckel and Dr. Sparrow at Brookhaven.

(Cont'd)

> Hence, we think that generally, a doctor only needs one reliable source of information showing that the plaintiff is ill and either a physical examination or medical records will suffice — but the doctor does need at least one of these sources.

Paoli II, 35 F.3d at 762 (emphasis added).

(See id. (witness's explanation).) As discussed by the court above, the instant tree study bears little methodological relationship to the Brookhaven studies. Therefore, the court cannot credit the rate of error assigned by Dr. Gunckel. Because no efforts were made to falsify the Gunckel hypothesis, the court finds that his conclusion can amount to nothing more than speculation and conjecture. As such, the potential for error is high. This factor will weigh against the admission of the tree study testimony.

4. Were There Standards Controlling the Techniques Operation?

a. Study of Human and Animal Health

Important standards that should have been controlling Dr. Gunckel's techniques were notably absent from his study of human and animal health. Specifically, Dr. Gunckel made no differential diagnosis, did not examine all relevant medical records, based significant portions of his opinion on anecdotal evidence and did not attempt to make any type of systematic survey of all TMI residents. This factor will weigh against the proffered testimony on the human and animal health study.

b. The Tree Study

The tree study is somewhat more controlled than the human and animal health study; however, it too appears to be missing important control standards. A question of fact has arisen as to whether Dr. Gunckel made a differential diagnosis with respect to the trees. His initial report and

deposition indicate that he did not, while an affidavit filed prior to the in limine hearing and his hearing testimony indicate that he did perform such a diagnosis. The court will presume that Dr. Gunckel's testimony at the hearing was truthful. (See Tr. at 1608-09.) As such, the court finds that there were some standards controlling the operation of the tree study. This factor will neither weigh against the admission of the tree study testimony nor weigh strongly in favor of the admission of that testimony.

5. Is the Methodology Generally Accepted?

a. Study of Human and Animal Health

Nothing before the court indicates that the methodology employed by Dr. Gunckel in conducting the human and animal health study is generally accepted by the relevant medical communities. Generally accepted medical opinions are not based solely upon anecdotal evidence.[39] The court has been presented with no other evidence aside from Dr. Gunckel's self-serving statements, that his human and animal study methodology is generally accepted. Accordingly, this factor will weigh against the admission of the proffered testimony.

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39. Wade-Greaux v. Whitehall Laboratories, Inc., 874 F.Supp. 1441, 1483 ((D.V.I.1994) ("Anecdotal human data . . . have inherent biases that make them unreliable. . . . [S]uch anecdotal human data do not represent the type of data reasonably relied upon by experts in the field. . . .").

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b. The Tree Study

The court cannot dispute that the methodologies employed by Dr. Gunckel and Dr. Sparrow at Brookhaven are generally accepted. Unfortunately, the tree study conducted by Dr. Gunckel in conjunction with the instant litigation bears little relation to the Brookhaven studies. Nothing on the record supports the contention that the specific methodology employed by Dr. Gunckel in the instant tree study is generally accepted. Dr. Gunckel's assurances to this effect are not enough. This factor will weigh against the admission of the proffered testimony.

6. Is There a Relationship Between the Technique and Methods That are Established to be Reliable?

The court has briefly discussed this factor in the context of other factors mentioned above. Dr. Gunckel's methodologies in both the study of human and animal health and the tree study differ in important respects from methodologies established to be reliable. In the health study, Dr. Gunckel relies extensively on anecdotal information and fails to give a differential diagnosis.[40] At the hearing he admitted to not reviewing any medical files (Tr. at 1645-46). Moreover, what the court finds most unreliable and unusual

40. In Paoli II, the Third Circuit noted that "while we think the standard techniques of differential diagnosis are reliable and will allow a doctor who employs them to testify to a novel conclusion, we also think that part of differential diagnosis is using these techniques to rule out alternative causes. Paoli II, 35 F.3d at 759 n. 27.

about Dr. Gunckel's medical testimony is that he is not a medical expert. Reliable methods allow qualified personnel to evaluate the data. In the tree study, Dr. Gunckel looks at damage in trees and extrapolates back to determine dose. This technique bears little relationship to his own pioneering standards of observing effects of known radiation doses through cellular and subcellular analysis. Based upon the foregoing, the court will weigh this factor against the admission of the proffered health and tree study testimony.

7. Qualifications of the Expert Based Upon the Methodology

a. Study of Human and Animal Health

Dr. Gunckel testified at his deposition that he is not a medical doctor, an epidemiologist, an immunologist, or a veterinarian. (Gunckel Dep. at 181-82.) He has not studied at all in the fields of human or veterinary medicine. (Id.) He has never diagnosed or treated people with acute radiation illness. (Id. at 169.) Moreover, his knowledge of animal and human health effects of radiation, by his own admission, was derived solely from literature reviewed in connection with his involvement in this litigation. (Id.) Although well-credentialed in his own field, Dr. Gunckel is not qualified to testify in the fields of medicine, epidemiology, immunology or veterinary medicine. Dr. Gunckel is therefore not qualified to give an expert opinion with respect to his human and animal health study.

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b. The Tree Study

It is without question that Dr. Gunckel is a pioneer in the area of studying radiation effects on plants. Defendants only attack on Dr. Gunckel's qualifications in this area is that Dr. Gunckel's work was conducted on seedlings rather than on mature spruce trees. (Gunckel Dep. at 165.) This is the second instance where Dr. Gunckel's deposition testimony is contradictory. As before, the court will construe the facts most favorably to Plaintiffs and presume that he has studied the effects of radiation exposure on mature trees. (See Dep. at 162.) Based upon the foregoing, the court finds Dr. Gunckel qualified to testify as to his tree study. This factor will weigh in favor of the admission of the proffered testimony.

8. Non-Judicial Uses of the Methodology

The court finds no evidence that the novel approach taken by Dr. Gunckel with respect to his methodology for the health study enjoys any use beyond the scope of this litigation. Similarly, the court finds there to be little practical application of the tree study methodology outside the confines of this case. That being said, the court finds this factor to be of little relevance to its overall analysis. Part of the reason that these methods enjoy no use beyond this litigation is that, thankfully, nuclear accidents are an aberration rather than the norm. This factor will not weigh against the admission of any of the proffered testimony.

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9. Other Factors

In its November 9, 1995 order, the court noted that the internal logical consistency of any hypothesis proffered would be a factor considered by the court when ruling on Defendants' motion in limine. Defendants contend that the dose that Dr. Gunckel establishes as the threshold for the observed tree damage is logically inconsistent with the doses he estimated for humans, with doses estimated by Plaintiffs' other experts, and to a large extent with the existence of human life. This criticism refers to Dr. Gunckel's claim that the observed tree damage resulted from a dose of approximately 1000 rem. Dr. Gunckel further testified that a dose of 360 rem would be fatal to fifty percent of the human population within sixty days ("LD50/60"). Thus, Dr. Gunckel's hypothesis regarding tree damage is logically inconsistent with the fact that the human mortality expected at a dose of 1000 rem did not occur. Dr. Gunckel attempts to explain the inconsistency by noting that the trees would have been outdoors during the entire accident and thus subject to a continuous dose of radiation. To the contrary, humans had the ability to go indoors and thereby lower the dose of radiation to which they were exposed. No testimony was offered to support the contention that trees could receive a dose equal to 1000 rem in the same area where persons staying indoors would receive a dose significantly less than 360 rem.

The court agrees with Defendants that Dr. Gunckel's hypothesis is logically inconsistent on this point. Standing alone, this factor would not militate in favor of excluding the proffered testimony. Taken together with the court's

analysis of the Daubert/Paoli II factors, however, this factor adds to the factors already weighing in favor of the exclusion of the proffered testimony.

C. Conclusion

Based upon the foregoing analysis, the court finds that the Daubert/Paoli II factors weigh decisively in favor of the exclusion of all of Dr. Gunckel's proffered testimony. Application of the factors demonstrates that Dr. Gunckel's methodologies lack scientific validity and reliability pursuant to Rule 702. Moreover, Dr. Gunckel lacks the qualifications to opine as a medical expert with respect to his human and animal health study. Because Dr. Gunckel is unable to verify his conclusion that the damage to the trees occurred at the time of the TMI accident, rather than at some earlier or later date, the proffered evidence also lacks the requisite Rule 702 "fit" with the instant litigation. Specifically, a jury would be unable to infer from Dr. Gunckel's testimony that the tree damage he discusses was in fact caused by the TMI accident. Finally, the portion of Dr. Gunckel's hypothesis related to dose is logically inconsistent with the lack of human casualties in the areas where tree damage was noted. The court will exclude all of Dr. Gunckel's proffered testimony.

IX. VLADIMIR A. SHEVCHENKO

Professor Shevchenko holds a Ph.D in Biological sciences, and has particular expertise in the area of radiation genetics; specifically with respect to the cellular and subcellular effects of radiation on plants. (Shevchenko Dep.

at 7-9.) Much of his expertise has been developed through his practical experience studying radiation effects in the Eastern Ural Radiation Belt region, at the site of the Kyshtym atomic weapons plant accident, at the site of the Chernobyl nuclear power plant accident, at the Semipalatinsk Polygon, and at the sites of nuclear experiments in the Alti Region. (7/6/94 Shevchenko Rpt. at 2-3.) Professor Shevchenko has filed two reports with the court. The first report, filed July 6, 1994, discusses the tree study performed by Professor Shevchenko on damaged trees in the TMI area. The second report, filed February 21, 1995, summarizes four studies conducted by other Russian scientists.[41] On November 9,

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41. These reports are as follows:

1. "Report of conducted dendrometric investigated samples of pine and spruce wood collected in the region of accident on NPS Three Mile Island," written by A. Tascaev and G. Kozubov, dated February 17, 1995 (hereinafter "Kozubov Rpt.");

2. "Experimental determination of gamma-radiation accrued dose and beta radiation assessment, in porcelain insulators (samples 1-9) after TMI accident," written by V. Popov and A. Portman, dated January 6, 1995 (hereinafter "Popov Rpt.");

3. "Results of immunological analysis of blood of people living around TMI," by O. Tarasenko, dated February 15, 1995 (hereinafter "Tarasenko Rpt.");

4. "Cytogenetic analysis of the people living in the neighborhood of TMI nuclear Power Plant [sic]," by G. Snigiryova, dated March 15, 1995 (hereinafter "Snigiryova Rpt.").

1995, this court issued a preliminary order which, inter alia, prohibits any expert from testifying to the substance of a report conducted by a different expert. In re TMI, No. 88-1452 at 2 (M.D.Pa. November 9, 1995) (preliminary order granting limited portion of Defendants' motion in limine). Based upon the 11/9/95 order, Professor Shevchenko was prohibited from testifying as to the substance of the Kozubov, Popov and Tarasenko reports. See infra, § XII. The court did ultimately permit Professor Shevchenko to opine as to the Snigiryova report as the court found the substance of this report to be within Professor Shevchenko's area of expertise. As such, Professor Shevchenko was capable of interpreting the data utilized and results obtained by Dr. Snigiryova, thereby affording Defendants the opportunity for meaningful cross-examination.

The court will next evaluate the proffered Shevchenko testimony pursuant to the Daubert/Paoli II factors. Separate analyses will be conducted for both the 7/6/94 tree study report and the 3/15/95 cytogenetic study of Dr. Snigiryova. Additional facts will be incorporated into the court's analysis where necessary.

A. Daubert/Paoli II Factor Analysis

1. Does the Method Consist of a Testable Hypothesis?

a. 7/6/94 Tree Study Report

Professor Shevchenko visited the TMI area to study trees allegedly damaged during the TMI accident. While in the

area, Professor Shevchenko was directed to the location of some of the damaged trees by Dr. Gunckel and Norman Aamodt.[42] (Shevchenko Dep. at 62-67.) Professor Shevchenko claims that he also selected some of the trees on his own. (Id.) In his report, Professor Shevchenko opines that tree damage observed in the TMI area is consistent with observations he has made at the Russian accident sites that he has studied. According to Plaintiffs, Professor Shevchenko's hypothesis is that "the data reflected a release of radioactivity that was of a sufficient harmful dose to cause injury and radiation effects to trees, and . . . [that] quantification of the amount of radioactivity released could be made from the data provided by the evaluation of the trees." (Pls.' Findings at 48.) This hypothesis is testable insofar as a scientist could examine the subject trees and determine whether there are other potential causes for the damage exhibited by the trees. A portion of the methodology, however, is not as readily testable.

Professor Shevchenko's methodology was described by Plaintiffs as follows:

> The methodology consisted of visual observation of trees in the TMI area, comparing the types and kinds of damages of the trees in the TMI area to trees observed in Chernobyl and damages in the gamma fields and making a professional judgment as to whether the damages and effects manifested by the trees in the TMI area reflected radiation exposure and dose within a specific range.

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42. Norman Aamodt is a consultant for Plaintiffs.

(Id. at 48-49.) This portion of the hypothesis could only be tested by a person with the same type of background as Professor Shevchenko. Only someone who has been privy to the extensive on-site observation of nuclear accidents as Professor Shevchenko would be capable of judging whether radiation damage occurred based merely upon viewing a tree. Even with credentials and experience as impressive as Professor Shevchenko, the court questions the ability of any scientist to make a "radiation diagnosis" based upon little more than a visual comparison. Moreover, Plaintiffs have not identified evidence showing that Professor Shevchenko has developed a database of his tree observations, or that other scientists could access such a database if necessary.

The question as to whether the tree study methodology is testable is close. However, Professor Shevchenko did testify that he examined and ruled out all other potential causes of tree damage akin to the damage exhibited by the TMI trees. (Tr. at 1169-70.) This differential diagnosis, combined with Professor Shevchenko's vast experience lead the court to believe that his methodology is testable and that it was tested by Professor Shevchenko. Accordingly, this factor will not weigh against the admission of the tree study testimony.

b. 3/15/95 Snigiryova Cytogenetic Report

Through its order dated November 9, 1995, this court permitted Professor Shevchenko to testify to the substance of the Snigiryova cytogenetic report. The hypothesis with respect to this report was that the TMI accident resulted in exposures and dose to persons in the TMI area reflected by

an elevated number of chromosomal abnormalities. Specifically, Dr. Shevchenko believed that if radiation levels were higher than naturally occurring background levels, this would be reflected in a higher than average rate of chromosomal abnormalities. The methodology employed by Professor Shevchenko to test his hypothesis involved analyzing blood samples taken from persons living in the TMI area and looking for chromosome aberrations.

The blood samples for the cytogenetic study were collected by Plaintiffs' attorneys and provided to Professor Shevchenko and Dr. Snigiryova. (Tr. at 1388.) The cytogenetic method of dose reconstruction involves the identification under the microscope and scoring of chromosome aberrations in circulating lymphocytes in the blood. (3/15/95 Snigiryova Rpt. at 1-2.) The particular type of chromosome aberrations that the study focused on are called dicentrics.[43] (Id. at 6-7.) A highly elevated frequency of dicentrics in a study group is indicative of radiation exposure. (Id. at 23.)

The court finds the hypothesis to be testable in that anyone with access to the blood samples could perform a similar analysis to verify the hypothesis. This factor will weigh in favor of the admission of the proffered cytogenetic testimony.

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43. A dicentric is an interim aberration of a chromosome. It describes a chromosome that has two centrimeres rather than one.

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2. Has the Methodology Been Subject to Peer Review?

a. 7/6/94 Tree Study Report

As with Dr. Gunckel, Plaintiffs contend that the published works of Dr. Gunckel and Dr. Sparrow evidence the peer review of the methodology employed by Professor Shevchenko. However, as the court discussed above, the methodology employed in examining trees in the TMI area bears little resemblance to the methodology peer reviewed in the Gunckel/Sparrow publications. Further, articles written about morphological damage observed in radiation-exposed trees, at best, establish a relation between exposure and effect, not that such observations are useful as a dose reconstruction method. The court cannot find evidence that the methodology of basing an opinion as to possible radiation exposure almost completely on visual inspection has been peer reviewed. Accordingly, this factor will weigh against the admission of the proffered testimony.

b. 3/15/95 Snigiryova Cytogenetic Report

Evidence has been presented indicating that the methodology employed by Dr. Snigiryova in the cytogenetic analysis is a standard methodology. (See Tr. at 343-401 (Testimony of Dr. Michael Bender).) The method has been subject to and withstood extensive peer review. (Tr. at 1171, 1406.) Defendants have raised an issue as to the propriety of the control group utilized by Dr. Snigiryova; however, as will be discussed infra, the court does not find this factor to substantially effect the validity of the methodology. This

issue goes to weight rather than admissibility. Consequently, this factor will weigh in favor of the proffered cytogenetic testimony.

3. Is There a Known or Potential Rate of Error?

a. 7/6/94 Tree Study Report

No specific rate of error was assigned to the tree study. Professor Shevchenko, instead, merely testified that he had studied enough trees to be confident that his conclusions were reliable to a reasonable degree of scientific certainty. (Tr. at 758.) Because so much of the methodology depends solely upon Professor Shevchenko's comparative observations, an error in his judgment or recollection could significantly alter the conclusions reached. As such, it is impossible for the court to quantify this factor. Finding Professor Shevchenko's vast experience to lend credence to his confidence in his results, this court will not weigh this factor against the admission of the proffered testimony; however, due to the inherently non-precise nature of this methodology, this factor will neither be weighed in favor of the admission of the proffered testimony.

b. 3/15/95 Snigiryova Cytogenetic Report

Dose reconstruction through cytogenetic analysis is an accepted and accurate method of dose reconstruction. The accuracy of the results, however, decreases as time elapses between exposure and testing. Plaintiffs have failed to introduce examples of other dose reconstruction efforts using the dicentric method conducted after so much time has

elapsed since the alleged exposure. The passage of more than one decade from the alleged time of exposure to the execution of the dicentric study increases the potential rate of error of the study. Further, questions about the appropriateness of the control group (e.g. whether the historical Russian control group adequately controls for background radiation of a TMI area study population) tend to increase the potential for an erroneous conclusion. The court, however, finds these factors to go more to the weight to be accorded the testimony than to its admissibility. Accordingly, this factor will not weigh against the admission of the proffered cytogenetic testimony.

4. Were There Standards Controlling the Technique's Operation?

a. 7/6/94 Tree Study Report

Plaintiffs contend that there were proper standards controlling Professor Shevchenko's tree study insofar as he studied a control group of trees in addition to the study trees. Further, Professor Shevchenko testified at the hearing, contrary to his report, that he did perform differential diagnosis to determine other possible causes of the tree damage. (Tr. at 1091-92.) The court finds that Professor Shevchenko did employ two of the most important standards to control the operation of his study. Accordingly, despite the absence of other types of controls, this factor will not weigh against the admission of the proffered tree study testimony.

b. 3/15/95 Snigiryova Cytogenetic Report

"Cytogenetic evaluation requires carefully controlled studies using analytical techniques not available in most laboratories."[44] The methodology as performed by Drs. Shevchenko and Snigiryova did not employ several standards generally used to control the technique's operation. Most significantly, the FISH method was not employed. This is the only method recognized in the literature as useful for assessing dose when so much time has elapsed since the alleged exposure. Further, the study did not attempt to match the presence in controls of potential confounders, such as age, gender or smoking. The data was not partitioned in accordance with these criteria to confirm that a confounder did not explain the presence of high dicentric counts. The court finds that important standards necessary to control the technique's operation were absent from the cytogenetic study. Thus, this factor will weigh against the admission of the proffered cytogenetic testimony.

5. Is the Methodology Generally Accepted?

a. 7/6/94 Tree Study Report

In support of their contention that Professor Shevchenko's tree study methodology is generally accepted, Plaintiffs point to Professor Shevchenko's "Bibliography"

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44. Brent Carson, "Increased Risk of Disease from Hazardous Waste: A Proposal for Judicial Relief," 60 Wa.L.Rev. 635, 643 (1985); see id. at 643 n. 40 (identifying the Center for Disease Control's follow-up assessment of Love Canal as a carefully controlled study).

which lists the hundreds of publications he has authored and co-authored. While the list is certainly impressive, it has little relevance to the issue of whether or not the methodology employed in the instant tree study is generally accepted. Most importantly, the court notes that while the majority of the listed publications are on the subject of the effects of radiation in plants, most of these publications deal with effects at the cellular and subcellular levels. Moreover, the court was unable to find any publication dealing with the comparative symptomology diagnosis employed by Professor Shevchenko in the instant study. Accordingly, the court finds that Professor Shevchenko's retrospective dose reconstruction through the observation of damage to tree tops is not a generally accepted method for reconstructing dose. This factor will weigh against the admission of the proffered tree study testimony.

b. 3/15/95 Snigiryova Cytogenetic Report

The parties do not disagree that dose reconstruction through cytogenetic analysis is a generally accepted method. Defendants question whether the instant study would fall within the generally accepted category due to the length of time that elapsed between the accident and the analysis of the study blood samples. The court finds that this issue goes more to weight than admissibility. As such, this factor will not weigh against the admission of the proffered cytogenetic testimony.

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6. Is There a Relationship Between the Technique and Methods That are Established to be Reliable?

a. 7/6/94 Tree Study Report

The court is unable to find an established and reliable method for back-calculating dose from observation of damage to trees due to the apparent novelty of the method. Accordingly, this factor is not helpful to the court in evaluating the reliability of the proffered testimony. This factor will weigh neither in favor nor against the admission of the proffered tree study testimony.

b. 3/15/95 Snigiryova Cytogenetic Report

The instant report bears a close relationship to cytogenetic analysis methodologies considered to be established and reliable. The most striking dissimilarities appear to be with respect to the length of time that has elapsed since exposure, and with respect to the selection of the control group. As was discussed above, the court finds that these factors go to weight rather than admissibility. Thus, it is of little consequence that the instant methodology differs from established and reliable methodologies in these ways. This factor will militate in favor of the admission of the proffered cytogenetic testimony. However, the weight accorded the testimony may be diminished due to the aforementioned flaws.

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7. Qualifications of the Expert Based Upon the Methodology

Defendants have not challenged the qualifications of Professor Shevchenko with respect to either the tree study or the cytogenetic analysis. Accordingly, this factor will weigh in favor of the admission of the proffered testimony.

8. Non-Judicial Uses of the Methodology

a. 7/6/94 Tree Study Report

For decades scientists such as Drs. Gunckel and Sparrow and Professor Shevchenko have been observing the effect of radiation on plants. In general, these studies have consisted of subjecting a plant to a known quantity of radiation and then observing the plant's reaction over time. Professor Shevchenko has also had the opportunity to observe the effect of radiation on trees based upon his visits to radiation exposed sites within the former Soviet Union. All of these studies and observations have been conducted in non-judicial settings. The observations made by Professor Shevchenko in the TMI area were made for the purposes of this litigation. It is unclear whether the technique employed by Dr. Shevchenko has been used extensively in non-judicial settings. The court, however, presumes that Dr. Shevchenko has employed this type of observational analysis when examining trees within exposed regions of the former Soviet Union. Due to the court's own uncertainty with respect to the importance of this factor to the instant analysis, the court will weigh this factor neither in favor nor against the admission of the proffered testimony.

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b. 3/15/95 Snigiryova Cytogenetic Report

The parties appear to agree that dose reconstruction through cytogenetic analysis has extensive use outside the present judicial setting. Accordingly, this factor will weigh in favor of the admission of the proffered cytogenetic testimony.

9. Other Factors

Through its November 9, 1995 order, the court identified to the parties factors beyond the Daubert/Paoli II factors that it deemed to be particularly important to this case. These factors included falsifiability, logical consistency, consistency with accepted theories and precision. In re TMI, No. 88-1452 at 4 (M.D.Pa. November 9, 1995) (order explaining factors the court would consider in ruling on the motion in limine). Defendants have attacked Professor Shevchenko's proffered testimony with respect to a number of these factors.

First, Defendants contend that the Shevchenko tree study report is not logically consistent with Professor Shevchenko's testimony at the hearings. (Defs.' Findings at 139-40, ¶ 19.) The court agrees that some of the hearing testimony of Professor Shevchenko and others tends to contradict the Shevchenko hypothesis. These contradictions support the contention that Professor Shevchenko failed to subject his hypothesis to rigorous empirical testing.[45] While these

45. As Defendants note, Professor Shevchenko does not explain why the doses found in other studies he commissioned are lower (Cont'd)

examples evidence a degree of logical inconsistency with respect to the tree study, the court finds that the inconsistency is not significant enough to militate in favor of the exclusion of the proffered testimony. This factor will not weigh against the admission of the tree study testimony.

Second, Defendants contend that Professor Shevchenko did not attempt to falsify his cytogenetic findings by making dicentric counts of individuals who were measured by whole body counts, or who lived near TLDs, even though he testified that both whole body counts and TLD dosimetry were used in the development of the cytogenetic dose response curves in his Russian work. (Shevchenko Dep. at 221; Tr. at 1373, 1379.) The court agrees that Defendants have pointed to a flaw in Professor Shevchenko's study design, however, the court cannot agree that this flaw dooms his proffered testimony in this area. The effect of his failure to falsify through comparison with TLDs and persons measured by whole body counts will go to weight rather than admissibility. Accordingly, this factor will not weigh against the admission of the proffered cytogenetic testimony.

Next, Defendants raise several issues which do not neatly fit within any of the categories discussed above. The court will now briefly touch upon those issues. First, Defendants raise an issue regarding the alleged time of death of the

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(Cont'd)
than the threshold doses required to cause the morphological damage he observed in the TMI trees. Moreover, after claiming that the sublethal exposure experienced by TMI trees would take several years to cause death at the tree tops, he attributed damage to tree tops discovered only months after the accident to radiation damage.

damaged tree tops. Professor Shevchenko testified that he used the dendrometric method to date the time of death of the tree tops. Nothing in Professor Shevchenko's report indicates that he relied upon this method to determine the time of death of the tree tops. However, as in previous sections, the court will presume that the witness testified truthfully at the hearing. Professor Shevchenko's statement is, however, contradicted by the report of Dr. Kozubov which indicates that the performance of the dendrometric analysis was based upon the assumption that the tree death occurred in approximately 1979. Accordingly, it is unclear how Professor Shevchenko determined when the tree tops died. It is evident that the time of death is related to determining the cause of the tree top death. If Professor Shevchenko merely presumed that the trees died within a few years of the TMI accident, his finding that radiation was the cause of death becomes less reliable. To the contrary, if Professor Shevchenko determined scientifically that the tree top death occurred within a few years of the TMI accident, it would strengthen his finding that radiation exposure was the cause of death. The court finds that this issue goes to the weight rather than the reliability of Professor Shevchenko's testimony. Accordingly, this factor will not weigh against the admission of the proffered testimony.

Second, with respect to the proffered cytogenetic testimony, Defendants raise an issue related to the propriety of the control group. Defendants contend that the cytogenetic analysis is flawed because Professor Shevchenko and Dr. Snigiryova did not employ a contemporaneous and geographically proximate control group. The effect of this, Defendants argue, is that it produces an erroneous

background count for "normal" levels of dicentric chromosomes. Plaintiffs did, however, present testimony which showed that the historical Russian controls used by Professor Shevchenko and Dr. Snigiryova had background dicentric counts virtually identical to those of a control group measured at Hershey Medical Center in Hershey, Pennsylvania. (Tr. at 705.) The court finds that Plaintiffs have come forward with sufficient evidence to demonstrate that their control group, while not contemporaneous and geographically proximate, is adequate.

Finally, Defendants question the admissibility of certain testimony in light of Rule 26 of the Federal Rules of Civil Procedure. Defendants argue as follows:

> Testimony about methodological steps that were not identified in an expert report violates the disclosure requirement of Rule 26. Federal Rule of Civil Procedure 26(2)(B), as amended in 1993, requires that testifying experts submit a written report which "shall contain a complete statement of all opinions to be expressed and the basis and reasons therefor." (emphasis added). Contrary to the assertion of plaintiffs' counsel during the hearing, the 1993 amendment did not merely recodify the status quo for expert discovery. The Advisory Committee Notes for the amended rule make clear that "a detailed and complete written report must be submitted." Fed.R.Civ.P. 26(a)(2)(B) advisory committee notes (emphasis added). The note further provides that "[t]he information disclosed under the former rule in

> answering interrogatories about the 'substance' of expert testimony was frequently so sketchy and vague that it rarely dispensed with the need to depose the expert and often was even of little help in preparing for a deposition of the witness. Revised Rule 37(c)(1) provides an incentive for full disclosure; namely, that a party will not ordinarily be permitted to use on direct examination any expert testimony not so disclosed. Id. (emphasis added).

(Defs.' Findings at 132-33, ¶ 2.) Defendants' are most troubled by Professor Shevchenko's hearing testimony that he did compare his study trees to a control area. No such use of a control group was mentioned in his report. While the court agrees with Defendants that Professor Shevchenko should not be permitted to introduce opinions not discussed in his report, the court finds the admission of this particular testimony to be harmless. Defendants have six months to prepare to cross examine Professor Shevchenko on the issue of the control group that he utilized. Further, they will have the benefit of his report, deposition and hearing testimony to assist them. Accordingly, the court finds the Defendants argument to be inapposite to this particular piece of testimony. This factor will not weigh against the admission of the proffered tree study testimony.

B. Conclusion

Based upon the foregoing, the court finds the proffered tree study and cytogenetic testimony to be admissible. Defendants have made strong arguments in favor of the

exclusion of this testimony. The court found the majority of these arguments to be credible and well-placed. Heeding the "the 'liberal thrust' of the federal rules," however, the court finds that it cannot exclude the proffered testimony of Professor Shevchenko based upon Defendants arguments. Paoli II, 35 F.3d at 739 (citing Daubert, 509 U.S. at __, 113 S.Ct. at 2794). Vital to the courts decision on this matter is Professor Shevchenko's experience in the field. Likely more than any other expert before the court, Professor Shevchenko has had extensive first-hand experience examining the effects of radiation exposure. Since the early 1960s, Professor Shevchenko has been involved almost exclusively in studying the aftermath of nuclear accidents and nuclear testing at Kyshtym, the Eastern Ural Radiation Belt Region, Chernobyl, Semipalatinsk Polygon, and the Altai Region. Thus, what his testimony may lack in rigid conformity to technical standards is amply counterbalanced by his extensive experience.

X. STEVEN B. WING

Steven Wing, a Ph.D epidemiologist,[46] is currently a Professor of epidemiology at the University of North Carolina at Chapel Hill. (Tr. at 904.) He has filed two expert reports in this litigation. The first report, filed in January of

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46. "Epidemiology is the study of disease patterns in human populations. 'Attempts to define a relationship between a disease and a factor suspected of causing it.' " In re Joint Eastern and Southern Dist. Asbestos Litigation, 52 F.3d 1124, 1128 (2d Cir.1995) (quoting Brock v. Merrell Dow Pharmaceuticals, Inc., 874 F.2d 307, 311 (5th Cir.), modified on reh'g, 884 F.2d 166 (5th Cir.1989), cert. denied, 494 U.S. 1046, 110 S.Ct. 1511, 108 L.Ed.2d 646 (1990)).

1994, focuses on Dr. Wing's analysis of mortality rates in the TMI area. Steven Wing, "Mortality Trends in Relation to the Accident at Three Mile Island," January, 1994 (hereinafter "1/94 Wing Rpt.")[47] The second report, filed on February 25, 1995, is a reanalysis of the Susser/Hatch cancer incidence study. Steven Wing, "A Reanalysis of Cancer Incidence Near the Three Mile Island Nuclear Plant," February 25, 1995 (hereinafter "2/25/95 Wing Rpt.") Dr. Wing contends that the mortality and cancer data support the conclusion that persons in the TMI area were exposed to dangerous levels of radiation during the TMI accident. Defendants have challenged the admissibility of both of Dr. Wing's reports and testimony related thereto.

Before proceeding with its analysis of Dr. Wing's proffered testimony, the court notes that it will be guided in its inquiry by the following observations of the United States Court of Appeals for the Second Circuit:

> By its nature, epidemiology is ill-suited to lead a factfinder toward definitive answers, dealing as it does in statistical probabilities and the continual possibility of confounding causal factors. In light of the inherent uncertainty shrouding issues of probabilistic causation, the decision of a district court on whether plaintiff's epidemiological

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47. The court believes that this study can be characterized as an "ecological study." "Studies that collect data about the group as a whole are called ecological studies. Such studies are useful for identifying associations but generally are regarded by epidemiologists as 'weak.' " Research Manual at 132-33 (footnote omitted).

> evidence is sufficient to get to the jury should be guided by the well-established standards governing judgment as a matter of law — whether, viewed in the light most favorable to the non-moving party, "the evidence is such that, without weighing the credibility of the witness or otherwise considering the weight of the evidence, there can be but one conclusion as the verdict that reasonable [jurors] could have reached."
>
> Applied to epidemiological studies, the question is not whether there is some dispute about the validity or force of a given study, but rather it would be unreasonable for a rational jury to rely on that study to find causation by a preponderance of the evidence.

Asbestos Litigation, 52 F.3d at 1133 (citations omitted). The court will now proceed with an analysis of Dr. Wing's testimony.

A. Dr. Wing's Mortality Study

1. Proffered Testimony

Dr. Wing embarked upon the mortality trend study at the request of Norman Aamodt, a consultant for Plaintiffs. (1/94 Wing Rpt. at 3.) According to Dr. Wing, Mr. Aamodt came to him with the results of a mortality trend analysis that he had performed.[48] (Id.) According to the Aamodt

48. To the best of the court's knowledge, Mr. Aamodt is not an epidemiologist.

analysis, mortality rates for 1980 were higher than historical averages. Mr. Aamodt suggested to Dr. Wing that the increase in mortality rates supported his theory that "high doses of radiation to small populations residing on elevated terrain in the path of noble gas plumes from the TMI accident lead to deaths of some older people who were already in poor health. . . ." (Id. at 3.) After re-analyzing the data relied upon by Mr. Aamodt and reaching similar results, Dr. Wing agreed to perform a more extensive epidemiological study of mortality rates in the area.

Using a more sophisticated analysis than Mr. Aamodt, Dr. Wing was able to calculate age-adjusted death rates, and isolate by cause of death, for the time period in question. (Id. at 5.) Additionally, Dr. Wing included within his analysis a study of mortality trends in all Pennsylvania counties and nationwide during the 1970s and 1980s. Based upon his results, Dr. Wing concluded the following:

> The major findings of this study that are suggestive of an effect of the TMI accident on mortality are:
>
> 1. an elevation of 1980 mortality in the five counties around TMI amounting to about 490 more deaths than would have been expected from 1979 rates;
>
> 2. an increase in cancer mortality among young children in the five counties in 1980-82;
>
> 3. an increase of infectious disease death rates in the five counties after the accident; and

> 4. a geographic clustering of areas with higher-than-expected 1980 mortality in parts of Pennsylvania and the Middle Atlantic and New England States.
>
> These results, considered in the context of other studies and uncertainties about exposure estimates, may reflect mortality impacts of high-level radiation exposures from the 1979 accident at Three Mile Island.

(1/94 Wing Rpt. at 11 (emphasis added).)

2. Daubert/Paoli II Factor Analysis

Defendants chose not to analyze the mortality study through the Daubert/Paoli II factors based upon their belief that the study testimony should be excluded because it "draws no conclusion regarding accident doses based on that study, [and] it is [therefore] not helpful to the trier of fact." (Defs.' Findings at 172, ¶ 1.) The court's discussion of these factors will be drawn from the direct and cross examination of Dr. Wing. Defendants' challenge to the proffered testimony will be addressed following the court's review of the Daubert/Paoli II factors.

a. Does the Methodology Consist of a Testable Hypothesis?

At the in limine hearing, Dr. Wing stated his hypothesis as follows:

> That high doses of radiation to small populations residing on elevated terrain in the path of noble gas plumes from the TMI accident led to deaths of some older people who are already in poor health, and that a high post-accident death rate in these small groups appears as a relatively small elevation of mortality in the five-county population as a whole.

(Tr. at 923.) The court finds this hypothesis to be testable. Adjusting his data for age, Dr. Wing was able to test and verify his hypothesis. (Tr. at 923.) This factor will weigh in favor of the admission of the proffered mortality study testimony.

b. Has the Methodology Been Subject to Peer Review?

Dr. Wing testified that the particular study at issue has not been subject to peer review. (Tr. at 924.) He added, however, that he has authored similar studies using some of the same methods and data which have been subject to peer review. (Id.) The court finds that the methodology of the TMI mortality study has been peer reviewed. Dr. Wing used basic and accepted epidemiological techniques to conduct the study. This factor will weigh in favor of the admission of the proffered testimony.

c. Is There a Known or Potential Rate of Error?

According to his hearing testimony, Dr. Wing did not apply statistical significance testing to the mortality study.

(Id.) Dr. Wing implies that he has used another method to "assess issues of precision of the results." (Id. at 925.) The court is unable to ascertain the specifics of this method. Nevertheless, with respect to the limited and preliminary conclusion that this study presents (discussed infra), the court finds the rate of error to be moderately high. Accordingly, this factor will weigh only slightly in favor of the admission of the proffered mortality study testimony.

d. Were There Standards Controlling the Technique's Operation?

Because Dr. Wing's underlying methodology was elementary and followed standard procedures, the court finds that he employed basic standards to control the operation of the technique. (See Tr. at 925.) This factor will weigh in favor of the proffered testimony.

e. Is the Methodology Generally Accepted?

As the court has alluded to in its analysis of previous factors, the underlying methodology utilized by Dr. Wing is a standard and generally accepted epidemiological methodology. (Id.) This factor will weigh in favor of the admission of the proffered testimony.

f. Is There a Relationship Between the Technique and Other Methods Established to be Reliable?

Dr. Wing contends that "these [mortality] studies have been in the past used to address many questions about health

effects of agents on populations." (Tr. at 926.) Insofar as the study may be viewed as a method of addressing questions about possible radiation health effects, rather than as a means of generating conclusions about dose, the court finds that it bears a close resemblance to methods established to be reliable. This factor will weigh in favor of the admission of the proffered mortality study testimony.

g. The Qualifications of the Expert Based Upon the Methodology

Defendants do not challenge Dr. Wings qualifications. Moreover, the court finds him amply qualified to opine regarding his mortality study. This factor will weigh in favor of the admission of the proffered testimony.

h. Non-Judicial Uses

It is without question that mortality studies are used on a regular basis in non-judicial settings within the field of epidemiology. This factor will weigh in favor of the proffered testimony.

i. Conclusion

The Daubert/Paoli II factors weigh heavily in favor of the admission of the proffered mortality study testimony.

3. Rule 702 Fit and Rule 403 Confusion

When evaluating whether the proffered testimony "fits" within the case, the court must determine whether the

testimony will assist the fact finder in understanding a fact in issue. Paoli II, 35 F.3d at 743. Dr. Wing is proffered as an expert on "dose." Thus, his testimony should assist the trier of fact in determining or understanding something about the dose of radiation received by residents living in the TMI area during the accident. Dr. Wing's own characterization of his mortality study demonstrates the absence of "fit" with respect to the question of dose:

> But I emphasize that there are no radiation doses that we have for this analysis, or relative dose estimates. So it's not an analysis of the association between dose and mortality. It's an investigation of an observation that was originally made in Vital Statistics data to understand who experienced this in terms of the age groups, what causes of death in the local area showed this, and which did not.

(Tr. at 920-21 (emphasis added).) Through his report, Dr. Wing can testify about certain changes observed in area mortality rates during the time period that he studied. His conclusions suggest that there may be some correlation between some observed changes in the mortality rates and the TMI accident. Dr. Wing cannot at this stage in his research make any direct correlation between the TMI accident and certain increased mortality trends. As such, the court finds that his testimony would not help the trier of fact understand any fact in issue. Moreover, with respect to Rule 403, the court finds that admission of this testimony would unnecessarily confuse the jury. The study, at this point, is suggestive yet incomplete. Admission of testimony regarding the study results may lend an air of conclusiveness to the study that is not rightfully deserved.

These factors weigh heavily against the admission of the proffered mortality study testimony.

4. Conclusion

The court's analysis of the Daubert/Paoli II factors weigh decisively in favor of admitting the proffered testimony, while the court's Rule 702 fit and Rule 403 confusion inquiries weigh strongly against the admission of the testimony. The court finds, and the Daubert/Paoli II analysis supports the finding, that as far as the mortality study has been taken it is methodologically sound. The study lacks any definitive conclusion tying dose to mortality rates. Consequently, the court views the study as a starting point, or preliminary analysis, meant to be supplemented by further study and testing. Were the study complete, it could prove helpful to the trier of fact. Yet, as the study presently exists, it is incapable of presenting any conclusion relevant to the instant litigation. Accordingly, the court will exclude the proffered mortality study testimony pursuant to Rule 702 as lacking the requisite "fit" with the instant litigation.

B. Dr. Wing's Cancer Incidence Study

1. The Proffered Testimony

Dr. Wing's cancer incidence study is a reanalysis of the data collected in connection with the study of cancer incidence in the area around TMI undertaken by Maureen Hatch and M. Susser of Columbia University. The Susser/Hatch study sought to test the hypothesis that the risk of cancer may have been raised by exposure to radiation from

the accident. After dividing the TMI area into geographical study tracts, Drs. Susser and Hatch analyzed pre- and post-accident cancer incidence relative to dose within those study tracts. The Susser/Hatch study concluded that radiation exposure had not caused an increase in post-accident cancer incidence.

The Wing reanalysis of the Hatch data is based on the relationship between cancer incidence and accident exposures characterized by a single dose response line derived from the cancer incidence in all of the study tracts.[49] The dose response line has a rising slope when increased dose corresponds to an increased incidence of cancer, a zero slope indicating no change in cancer incidence with increased dose, or a negative slope indicating a decline in incidence corresponding to an increase in dose. (2/5/95 Wing Rpt. at 6; Walker Rpt. at 3; Tr. at 857-58, 937-38.) Statistical analysis is used to derive the slope of the dose response line which best fits the cancer incidence data across all study tracts. Dr. Wing determined the difference between the dose response lines in the pre-accident period (1976-1979) and the post-accident period (1981-1985). (Tr. at 937.) The Wing study shows a small increase in cancer incidence for all types of cancer, and more significant increases in the incidence of lung cancer and leukemia. (2/5/95 Wing Rpt. at 11.) Based upon these findings, Dr. Wing concludes that the increases are "consistent with allegations that the magnitude of

49. In contrast, dose assessments in the Susser/Hatch study were made on the basis of the Beyea dose estimates. These dose estimates were based upon original plant data, meteorologic data from the TMI meteorological tower, and a Gaussian plume model. (See Susser/Hatch Study at 400-01.)

radiation doses from the TMI accident were much higher than was assumed in the past." (Id.)

2. Daubert/Paoli II Factor Analysis

a. Does the Methodology Consist of a Testable Hypothesis?

Dr. Wing's hypothesis for his cancer incidence study is that accident emissions from TMI were sufficiently large to have caused measurable increases in cancers in the six years following the accident. Defendants agree with Plaintiffs that, in theory, this hypothesis is testable. The court finds that the cancer incidence study methodology consists of a testable hypothesis. Accordingly, this factor will weigh in favor of admitting the proffered testimony.

b. Has the Methodology Been Subject to Peer Review?

The cancer incidence study has not been subject to peer review. Dr. Wing has, however, provided testimony that data reanalyses such as the one he performed on the Susser/Hatch cancer incidence data are common within the field of epidemiology. Aside from Dr. Wing's "unadorned assertions" that the methodologies have been subject to peer review, Plaintiffs have presented no evidence of this fact. Daubert II, 43 F.3d at 1319. Consequently, the court is left to question whether "[p]ersonal opinion, not science, is testifying here." Id. While the court found Dr. Wing to be credible, and has no basis to question his word, the court cannot ignore that Plaintiffs have failed to carry their

evidentiary burden. Furthermore, the court finds that the existing legal precedent in this area clearly defines the burden that Plaintiffs must shoulder. This factor will weigh against the admission of the proffered testimony.

c. Is there a Known or Potential Rate of Error?

Plaintiffs contend that "the standard of error contained in the reanalysis is consistent with similar reanalyses that appear in the epidemiological literature." (Pls.' Findings at 35.) This statement is made without further explanation as to the precise rate of error that appears in "the epidemiological literature." Further, the court is given no citation to any of this literature. Tables 1-4, appended to the cancer incidence study identify the standard error in the calculations, yet no information is provided to assist the court in understanding these numbers.[50] Defendants, to the

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50. A recent article in the Harvard Law Review explained the importance of the "rate of error" factor in the context of the Daubert analysis. "Confronting the New Challenges of Scientific Evidence," 108 Harv.L.Rev. 1532 (May, 1995) (hereinafter "New Challenges"). In the article, the following is noted:

> In considering scientific reliability, judges will often need to address the statistical significance of scientific studies. Although Daubert itself raised the issue whether scientific evidence must meet a threshold level of statistical significance for admissibility, the Court did not speak to statistical significance, perhaps because it concluded that legal reliability embraces only scientific validity. Yet because significance testing, too, is central to a large body of scientific research, statistical inference

(Cont'd)

contrary, argue that the results of Dr. Wing's study are "ascribable to chance as well as to any real association with accident emissions." (Wing Dep. at 270-73.) Specifically, Defendants contend that when confidence intervals are calculated[51] for Dr. Wing's findings of an increased incidence of all cancers in the TMI population, they include values of a negative association between accident doses and the incidence of all cancers in the post-accident population. (Tr. at 971; Walker Rpt. at 5.) The same result is true with regard to the calculated increase in post-accident leukemia, (Tr. at 971; Wing Dep. at 270-73; Walker Rpt. at 5.); lung cancer was the exception, producing large error bands. (Wing Dep. at 270-73.) Defendants' experts Hoel and Walker testified

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(Cont'd)

> will frequentiy factor into Daubert's legal reliability prong. . . . Judicial inquiry into statistical significance is, therefore, necessary in determinations of scientific, and hence evidentiary, reliability.

Id. at 1535-36 (footnotes omitted). The article went on, observing that despite the importance of the evaluation of statistical significance, many judges were ill-equipped to perform such an analysis; and further, that many experts were often unprepared to discuss the statistical dimensions of their own studies. Id. at 1540.

51. The measures of standard error appearing in Dr. Wing's report can be used to calculate the size of the "confidence interval" surrounding the risk estimates derived from the data. (Tr. at 970.) A confidence interval sets forth the upper and lower bounds of the likely true result. A confidence interval of 95% encompasses that range of numbers within which the true result will fall 95% of the time. Wade-Greaux, 874 F.Supp. at 1452; Federal Judicial Center, Reference Manual on Scientific Evidence 154-55 (West 1994).

that lung cancer has never been identified with radiation exposure as an isolated effect, and that one would not expect lung cancer to occur within the time frame of the Wing analysis. (Tr. at 793, 795, 800, 878-79.)

On a related topic, Defendants question the accuracy of the report in light of the alleged failure of Dr. Wing to account for an appropriate latency period with respect to his lung cancer analysis. Evidence was presented at trial that the average latency period for lung cancer is 15 years. (Tr. at 783-84.) Dr. Wing's study results presume a radically decreased latency period. The court agrees that the latency question decreases the credibility of Dr. Wing's findings. Standing alone, this inconsistency is not enough, however, to draw into question the accuracy of all of the study findings.

The court is unwilling to accept Dr. Wing's bald assertion that the potential rate of error is standard, especially in light of evidence produced by Defendants tending to show a potentially high rate of error. Further, the court is cognizant that part of the difficulty in resolving this factor is due to the court's own uncertainty regarding Dr. Wing's standard error calculations. Thus, the court will, for the moment, defer ruling on this factor. If upon completing the remainder of its analysis, the court finds that the outcome of this factor is decisive as to the question of admissibility of the study testimony, the court will order Plaintiffs to provide a more direct and substantiated discussion of the error issue.

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d. Were There Standards Controlling the Technique's Operation?

A significant portion of Dr. Wing's report is devoted to discussing how he attempted to rule out factors that could serve to bias the study results. Further, a separate affidavit is provided explaining the care with which Dr. Wing and his associates reviewed the R-base data. At the hearings Dr. Wing testified that "[w]e were very careful with our work in documenting all our data processing. And, in fact, I believe it's because of our care and the thoroughness with which we approached the data that we received, that we discovered the errors and the mistakes in the previous [Susser/Hatch] report."

Despite this, Defendants point to several standards that Dr. Wing failed to utilize. Defendants contend that Dr. Wing failed to consider the biological plausibility of the results, failed to test the risk estimates derived from his statistical analysis against actual trends in cancer rates for the types of cancers known to be radiogenic, and to consider whether there were changes in proportions of such cancers in the population. Additionally, Defendants argue that Dr. Wing failed to consider whether actual mortality patterns in the population confirm the conclusion that there exist increased incidences of cancer in the population attributable to radiation exposure, and that he failed to evaluate the statistical evidence "in the context of the sensitivity of the findings to changes in assumptions and data, coherence of the evidence with other knowledge, the magnitude of associations, their consistency across groups, and temporal relationships of exposure and effect." (Tr. at 877.)

The court finds that although he did not employ all possible standards, there were some standards controlling the operation of Dr. Wing's techniques. This factor will not weigh against the admission of the proffered testimony.

e. Is the Methodology Generally Accepted?

Plaintiffs argue that Dr. Wing has performed a generic epidemiologic re-analysis, and that such re-analyses are common place and generally accepted. Defendants claim that while the statistical technique employed by Wing is generally accepted in the scientific community, his methodological approach regarding the data subject to that statistical analysis and the conclusions to be drawn from that analysis are not. Specifically, Defendants take issue with the methodology because it produces conclusions at odds with what is generally known and accepted about cancer latency periods. In theory, such a finding could prove that the methodology leading to the conclusion is necessarily flawed, or it could prove that previous assumptions regarding latency periods were incorrect. The court finds that this factor goes to the weight of the testimony rather than its admissibility. Only the lung cancer outcomes contradicted standard latency period assumptions. Thus, the leukemia and "all cancers" results could still prove helpful and relevant to a jury. This factor will not weigh against the admission of the proffered testimony.

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f. What is the Relationship of the Technique to Methods Established to be Reliable?

In many ways Wing's cancer incidence study closely resembles a standard and reliable epidemiological reanalysis. Yet, in one important way it does not. Dr. Wing's reanalysis produces no conclusive findings. When testifying at the in limine hearings Dr. Wing indicated that he had chosen carefully the wording of the conclusion to his report. (Tr. at 956.) Specifically, Dr. Wing's findings are nothing more than suggestive of an increase in cancer rates consistent with radiation exposure. Dr. Wing could not go so far as stating that his reanalysis suggested a dose response relationship. Thus, where an established and reliable methodology would be carried to the point of producing some form of conclusive findings, Dr. Wing's methodology does not. Accordingly, this factor weighs against the admission of the proffered testimony.

g. What are the Qualifications of the Expert With Respect to the Methodology?

Defendants have not challenged the qualifications of Dr. Wing. As such, and because the court finds him to be well credentialed, this factor will weigh in favor of the admission of the proffered testimony.

h. Non-Judicial Uses

Epidemiological re-analyses of data are performed on a daily basis in a variety of non-judicial settings. Although

the court has found that Dr. Wing's re-analysis varied from standard re-analyses in important ways, those variations are not material to this factor. When viewed as the starting point for a more complete epidemiological re-analysis, it is clear that the Wing methodology has non-judicial uses. This factor will weigh in favor of the proffered testimony.

i. Conclusion

The Daubert/Paoli II analysis militates slightly in favor of admitting the proffered testimony. However, the court has deferred ruling on one of the more important factors, that of the known or potential rate of error. Accordingly, should the testimony survive Defendants' Rule 702 "fit" challenge, the court will direct Plaintiffs to submit a more focused and explanatory discussion of the known or potential rate of error for the Wing cancer incidence re-analysis.

3. Rule 702 "Fit"

Defendants challenge the Wing study on the ground that it does not "fit" within the litigation. Specifically, Defendants argue that the study has no bearing on Plaintiffs' central thesis that the accident resulted in a narrowly dispersed plume that caused highly localized segments of the TMI population to be exposed to large amounts of radiation. This argument is based upon the fact that Dr. Wing did not utilize Plaintiffs' dose pattern estimates when conducting his study. Rather, Dr. Wing calculated dose in a manner more closely aligned with the original Susser/Hatch study. The court agrees that in some ways the Wing study does not "fit." The court's rationale is, however, based upon reasons other than those

mentioned by Defendants. That certain of Dr. Wing's findings are suggestive of increased cancer incidence consistent with radiation exposure is relevant and important. However, the strength of this finding is somewhat diminished by Dr. Wing's failure to explain the discrepancy between expected latency periods and his lung cancer findings.

Nevertheless, the court finds that a portion of the Wing cancer incidence reanalysis is relevant to a fact in issue, namely with respect to the dose of radiation received by Plaintiffs. The findings regarding leukemia and "all cancers" are suggestive of an increase. Such a finding could assist a jury in evaluating a fact in issue — the precise dose of radiation to which Plaintiffs were exposed. As such, the court will exclude only the study testimony related to the lung cancer findings as lacking the requisite "fit" with the captioned action.

4. Conclusion

Based upon the foregoing analysis, the court will exclude the portions of the Wing report dealing with lung cancer as lacking the requisite Rule 702 "fit." The court will defer ruling on the remainder of the proffered testimony until it is in receipt of Plaintiffs' supplemental discussion of the rate of error issue. Defendants will be entitled to respond briefly to Plaintiffs' supplemental filing should they so desire.

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XI. DOUGLAS CRAWFORD-BROWN

A. Proffered Testimony

Dr. Crawford-Brown, presently a full professor at the University of North Carolina, holds a Ph.D. in nuclear science and health physics. (Tr. at 1676-77.) Plaintiffs have proffered Dr. Crawford-Brown as an expert in exposure assessment. Dr. Crawford-Brown testified that exposure assessment is one of the distinct stages of a risk assessment. (Tr. at 1679.) The following definition of risk assessment was provided by Dr. Crawford-Brown:

> The formal definition [of risk assessment] that's required in the red book, or the guide for the federal government, Conducting of Risk Assessment, is that it's a process by which you first determine whether a substance or a risk agent is able to produce effects, and then you determine the amount of exposure or the amount of the substance that's in the environment, and the degree to which people are connected to it, and then you determine the relationship between exposure and the probability and severity of effects. And then you summarize that as an estimate of the probability and severity of effects and uncertainty distribution in a distribution of variability in the population.

(Tr. at 1678.) Plaintiffs have defined Dr. Crawford-Brown's role in the litigation as that of reviewer of the totality of the evidence and offerer of a final opinion as to whether

Plaintiffs' experts, as a whole, considered the types of evidence necessary to establish what dose or doses of radioactivity were delivered to the residents of the TMI area as a result of the TMI accident. Based upon the "separate considerations of evidence" described in his Affidavit, and "conditional on establishing that the effects noted were in most likelihood caused by radiation exposures," it is Dr. Crawford-Brown's opinion that the asserted effects "are consistent with the claim that individuals located in the vicinity of the points of biological dosimetry" considered by him "received dose equivalents in excess of 100 rem." (2/27/95 Crawford-Brown Aff. at 18.)

Of particular concern to the court throughout this in limine process was the issue of how Dr. Crawford-Brown's final opinion might be altered should the court find any or all of the evidence underlying his opinion to be inadmissible. During the pre-hearing conference, the court indicated to Plaintiffs that it "would like to find out what . . . [Dr. Crawford-Brown's] perception is on some of the findings he has relied on, how much confidence he has in them." (Tr. at 57.) Moreover, the court stressed that it "would like to know how his opinion in any way might be altered in light of what he may think about this material." (Tr. at 58.) As the prior sections of this memorandum indicate, a significant portion of Plaintiffs' proffered testimony will be excluded. Consequently, the court will evaluate the proffered testimony of Dr. Crawford-Brown in light of the decisions it has already made regarding Plaintiffs' other experts on dose.

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B. Daubert/Paoli II Analysis

1. Does the Methodology Consist of a Testable Hypothesis?

When questioned on this topic during the hearing, Dr. Crawford-Brown testified that his methodology did not involve a testable hypothesis. (Tr. at 1714.) Plaintiffs opine that due to the nature of Dr. Crawford-Brown's testimony, this issue is irrelevant. The court is less eager to offhandedly discard what the Supreme Court has identified as a "key" factor in the Daubert analysis. Daubert, 509 U.S. at __, 113 S.Ct. at 2796. Instead, the court finds the absence of a testable hypothesis to underscore the fundamental flaws in the Crawford-Brown methodology. As has been a recurring problem with all of Plaintiffs' experts, Dr. Crawford-Brown's testimony is rooted in an unproven assumption. Specifically, Dr. Crawford-Brown has presumed that all of the effects alleged by Plaintiffs (e.g. chromosome dicentrics, tree damage, human and animal health effects) were caused by radiation. It appears, at least in theory, that Plaintiffs assumed that each of their experts would succeed in validating the overall thesis that Plaintiffs' alleged injuries were caused by radiation emitted from TMI during the accident. Thus, Plaintiffs fashioned their expert testimony as a precarious house of cards with each expert relying on conclusions which other experts were responsible for generating and verifying. Because of this, the failure of even one of Plaintiffs' experts to produce a verifiable conclusion necessarily harms the conclusions of other of Plaintiffs' experts. Dr. Crawford-Brown provides the quintessential example of this perilous approach.

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Dr. Crawford-Brown's testimony could have been based upon a testable hypothesis. Rather than simply presume that radiation was the cause of the effects noted by Plaintiffs, Dr. Crawford-Brown could have preformed a full exposure assessment analysis, including an evaluation of the relative strength or weakness of each of the strands of evidence (e.g. biological dosimetry data) available to him.[52] Instead, he chose to rely blindly upon the conclusions generated by Plaintiffs other experts. Thus, contrary to Plaintiffs' argument, the court finds that Dr. Crawford-Brown's testimony does not by it's nature prevent the formation of a testable hypothesis. Rather, Dr. Crawford-Brown chose to

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52. During his deposition, Dr. Crawford-Brown admitted that in making an exposure assessment, ordinarily one would assess or weigh the strength of each of the kinds of evidence available:

> Science can't distinguish between the estimates. What it can say is something about the relative strength of each of the estimates — which ones you believe and which ones you disbelieve, to what degree do you believe them or disbelieve them.
>
> And then, in my work, anyway, that is then called a cumulative confidence distribution. You ask, now, considering all the lines of reasoning, how confident are you that it's less than one rem, ten rems, a hundred rems, a thousand rems, and so forth. And that assignment of confidence at any given dose [estimate] depends on how much you're weighing the various lines of evidence.

(Crawford-Brown Dep. at 56-57.) He did not make this type of assessment with respect to the TMI data.

design his methodology so as not to consist of a testable hypothesis. Consequently, this factor will weigh against the admission of the proffered testimony.

2. Has the Methodology Been Subject to Peer Review?

The methodology utilized by Dr. Crawford-Brown loosely resembles a traditional exposure assessment methodology. Insofar as this resemblance exists, the methodology has been subject to peer review. Dr. Crawford-Brown's methodology differs from the traditional model, however, in that he does not evaluate the relative strength of each of the strands of evidence upon which he relies. This twist on the traditional exposure assessment methodology has not been subject to peer review. Accordingly, this factor will weigh against the admission of the proffered testimony.

3. Is There a Known or Potential Rate of Error?

The rate of error of an exposure assessment is intimately connected to the rate of error of each of the pieces of evidence upon which the assessment relies. Consequently, the potential rate of error in Dr. Crawford-Brown's assessment is tied to the respective rates of error of Plaintiffs' other experts. The court, above, has found those rates of error to be uniformly high, with the exception of the Shevchenko testimony. Because Dr. Crawford-Brown's conclusion presumes the accuracy of the other experts' conclusions, and because the court has determined those experts' methodologies to have potentially high rates of error, the court finds the potential

rate of error of the Crawford-Brown methodology to be high. This factor will weigh against the admission of the proffered testimony.

4. Were There Standards Controlling the Technique's Operation?

Inasmuch as the experts' upon which Dr. Crawford-Brown relies had standards controlling the operation of their techniques, Dr. Crawford-Brown had standards controlling his. That being said, the court has already highlighted the important standard absent from the Crawford-Brown technique — the weighing of the relative strengths and weaknesses of the evidence he considered.

5. Is the Methodology Generally Accepted?

Exposure assessment is a generally accepted and helpful methodology. It is not a generally accepted practice to discard a key step in the standard methodology. Accordingly, because Dr. Crawford-Brown did not follow the standard methodology, the court cannot find the methodology he did employ to be generally accepted. This factor will weigh against the admission of the proffered testimony.

6. What is the Relationship of the Technique to Methods That are Established to be Reliable?

The comments that the court has made above speak to this factor. Dr. Crawford-Brown's exposure assessment bears some similarity to established and reliable methods.

However, he also fails to employ some techniques that would be expected in a traditional exposure assessment. This factor will weigh against the admission of the proffered testimony.

7. The Qualifications of the Expert Based Upon the Methodology

Defendants have not challenged Dr. Crawford-Brown's qualifications. As the court finds him well qualified, this factor will weigh in favor of the admission of the proffered testimony.

8. Non-Judicial Uses

There is no question that exposure assessment is applied with frequency in a variety of non-judicial settings. The version of exposure assessment applied by Dr. Crawford-Brown in this litigation, however, appears specifically tailored to the legal setting. Dr. Crawford-Brown was presented with a set of conclusions and supporting evidence which he was directed to credit as being true. Based upon these assumptions, he was then asked to state whether the assumptions were consistent with the thesis that the TMI population was exposed to unsafe levels of radiation during the TMI accident. With the caveat that he assumed it could be proven that radiation was the cause of the observed effects, Dr. Crawford-Brown conducted a limited exposure assessment which revealed the evidence to be consistent with Plaintiffs' thesis. The court cannot imagine how such a methodology would have any practical use in a non-judicial setting where the objective would seem to be seeking answers to difficult questions, rather than seeking to verify a thesis

via circular reasoning.[53] This factor will weigh against the admission of the proffered testimony.

9. Conclusion

The Daubert /Paoli II analysis weighs decisively in favor of excluding the proffered testimony. As the United States District Court for the Northern District of Indiana noted in Dana Corp.:

> [Plaintiff's expert] based his opinions on his understanding of what various depositions reported, and he may do that under Rule 703. But an expert's opinion that is without foundation is worth nothing as evidence, and is so irrelevant for purposes of Rule 402 and not reliable for purposes of Rule 702 as construed by Daubert. In the instances in which the record provides no such foundation, . . . [the expert's] opinion adds nothing to the question of [whether plaintiffs were exposed to radiation as a result of the TMI accident].

The proffered testimony of Dr. Crawford-Brown will be excluded as unreliable pursuant to Rule 702 and irrelevant for purposes of Rule 402.

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53. In fact, Dr. Crawford-Brown expressed his reservation that he was "kind of worried about having this circularity" in using incidence data to estimate doses, based on the assumption that doses were the cause of any increased incidence. (Crawford-Brown Dep. at 110-11.)

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XII. BRUCE MOLHOLT

A. Proffered Testimony

Bruce Molholt has filed several reports with the court. His 4/8/93 report setting forth his opinion that depressed lymphocyte counts could be used to back-calculate a radiation exposure dose was the subject of Defendants' first motion in limine on dose issues. In fact, it was through the briefing of that motion in limine that the court determined that Daubert hearings were necessary. A second report, dated March 13, 1995, purported to perform a risk assessment on the TMI test Plaintiffs to determine whether the cancers they developed following the TMI accident were more likely than not due to radiation exposure as a result of the accident. (3/13/95 Molholt Rpt. 3.) Finally, in connection with the court's request for supplemental briefing on Defendants' original motion in limine, Plaintiffs submitted a final Molholt report, dated May 1, 1995. It was in this final report that Molholt articulated his "corollary hypotheses" as follows:

> Furthermore, as corollary hypotheses, if radionuclides were released during the TMI accident sufficient to expose nearby persons to . . . [greater than or equal to] 100 rems, then there should have been additional multiple phenomena observable in the surrounding human population, flora and fauna both immediately and long-term. The expected sequelae from exposure to . . . [greater than or equal to] 100 rem include the following additional ten phenomena which expand the data set from which to reconstruct radiation dosimetry:

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* Erythema, eye irritation, nausea, vomiting and hair loss,

* Metallic and iodine tastes and smells,

* Radioiodines in excess in local fauna,

* Increased neonatal hypothyroidism from radioiodine emissions,

* Increased incidence of adult thyroid diseases,

* Increased infectious diseases in exposed persons,

* Increased infectious diseases in exposed animals,

* Increased incidence of autoimmune diseases,

* Increased incidence of cancer, and

* Radiation damage to trees.

Supporting relevant scientific data for these ten additional corollary hypotheses are summarized below. Taken together with fulfillment of the two predictions of the first hypothesis, fulfillment of the predictions afforded by these additional ten hypotheses comprise a very convincing biodosimetry data set that radiation exposures

exceeded doses of 100 rem during the TMI accident.

(5/1/95 Molholt Rpt. at 4-5.)

At the in limine hearing, Plaintiffs withdrew the proffered immunosuppression testimony of Dr. Molholt. (Tr. at 681.) Plaintiffs made this withdrawal with the caveat that they would not withdraw Dr. Molholt's opinion as to his "corollary hypotheses" to the extent they "addressed the relevance of other indicators of different levels of exposure." (Id. at 684.) Defendants now challenge the "corollary hypotheses" on the ground that they are simply naked assertions of the alleged conclusions of analyses performed by others, and as such, lack any indicia of scientific reliability. Plaintiffs first submit that the discussion of the corollary hypotheses testimony should be continued to the February, 1996, in limine hearings on medical causation. Further, they argue that such postponement is logical insofar as the corollary hypotheses are intertwined with the toxicological aspect of Dr. Molholt's causation report. The court is not entirely convinced of Plaintiffs' argument, but it is willing to give them the benefit of the doubt in reserving ruling on this issue until the conclusion of the February in limine hearings. In reserving judgment on this issue, the court expects that Dr. Molholt will testify at the hearings. Should Plaintiffs fail to produce Dr. Molholt, the court reserves the right to exclude his testimony on that basis alone.

That being said, the court has serious questions regarding the admissibility of the corollary hypotheses now that Plaintiffs have withdrawn the immunosuppression

hypothesis. Dr. Molholt states in his report that the corollary hypotheses are meant to be considered in conjunction with the immunosuppression hypothesis. Accordingly, Dr. Molholt will need to offer convincing testimony, based upon his reports that are already of record, that the corollary hypotheses can stand alone. Moreover, Plaintiffs are hereby placed on notice that with respect to Dr. Molholt, the court finds the issues raised in Defendants findings of fact and conclusions of law to be extremely persuasive. To convince this court of the reliability of his testimony, Dr. Molholt, and any other expert that testifies in support of his reports, will have to directly and succinctly rebut the challenges made and flaws exposed in Defendants' findings.

Based upon the foregoing, the court will defer ruling on the admissibility of the Molholt corollary hypothesis pending his participation in the upcoming in limine hearings on medical causation.

XIII. RATIONALE BEHIND THE PRELIMINARY ORDER DATED 11/9/95

On November 9, 1995, immediately following a lengthy prehearing conference, this court issued a preliminary order granting limited portions of Defendants' motion in limine. Due to the time pressures attendant to issuing that order, the court deferred issuing a memorandum of law until a later date. The court is now prepared to explain the rationale supporting its November 9 order.

Appendix G

A. Untimely Filing of Expert Reports on Dose

The testimony of experts named in ¶ 1 of the 11/9/95 order were excluded based upon the untimely filing of their expert reports. Through an order dated November 13, 1994, this court set the deadline for the filing of Plaintiffs' expert reports as March 1, 1995. As the parties are aware, case management has been a recurring problem in this litigation. Exasperated by the parties consistent failure to abide by any case management schedule, the court, with the agreement of the parties, imposed a rigid case management schedule aimed at seeing this case to trial in June of 1996.[54] The court has repeatedly stressed its unwillingness to depart from this schedule absent the most compelling circumstances. See, e.g., Order dated 11/13/94 ("All deadlines stated in the schedule are binding deadlines. No changes in deadlines, nor extensions of time will be grated absent extreme and compelling circumstances."); Order dated 4/28/95 ("[T]he deadlines set by the November 2, 1994 joint case management schedule are binding.").

Rule 26 of the Federal Rules of Civil Procedure provides the following with respect to the filing of expert reports:

> The report shall contain a complete statement of all opinions to be expressed and the basis and reasons therefor; the data or other information considered by the witness in forming the opinions

54. The Civil Justice Reform Act of 1990, 28 U.S.C. § 473(a), requires federal trial court judges "to implement techniques and strategies designed to dispose of cases in an efficient and inexpensive manner." Capek v. Mendelson, 143 F.R.D. 97, 99 (E.D.Pa.1992).

> . . . the qualifications of the witness, including a list of all publications authored by the witness within the preceding ten years; the compensation to be paid for the study and testimony; and a listing of any other cases in which the witness has testified as an expert at trial or by deposition within the preceding four years.
>
> (C) These disclosures shall be made at the times and in the sequence directed by the court.

Fed.R.Civ.P. 26(a)(2)(B) and (C). This court directed the disclosure of Plaintiffs' expert reports on dose to occur on March 1, 1995. On the eve of the in limine hearing, some eight months later and without an explanation, Plaintiffs attempted to introduce new reports for a total of ten experts. Moreover, the bulk of these reports were to be delivered by previously unidentified experts. In Daubert, the Supreme Court drew an important line in the sand in reference to the evolving nature of scientific testimony:

> Scientific conclusions are subject to perpetual revision. Law, on the other hand, must resolve disputes finally and quickly. . . . We recognize that in practice, a gatekeeping rōle for the judge, no matter how flexible, inevitably on occasion will prevent the jury from learning of authentic insights and innovations.

Daubert, 509 U.S. at __, 113 S.Ct. at 2798; see Margaret A. Berger, Procedural Paradigms for Applying the Daubert Test, 78 Minn.L.Rev. 1345, 1372-73 (1994) ("[C]ourts should not

allow the . . . [proponent of the expert testimony] to rely on affidavits from expert witnesses whose identity and reports were disclosed, but who now wish to raise new issues about which the . . . [opposing party] never had notice.")

This court, heeding the Supreme Court's observation, must draw its own line in the sand. Sempier v. Johnson & Higgins, 45 F.3d 724, 734 (3d Cir.1995) ("Under Federal Rules of Civil Procedure and our jurisprudence, district courts have broad discretion to manage discovery."), cert. denied 515 U.S. __, 115 S.Ct. 2611, 132 L.Ed.2d 854 (1995). For litigation purposes, the facts of this case must at some point become complete. Whether the facts, for other non-litigation purposes, continue to evolve is necessarily of little matter to the court. A decision which has the finality of a legal decision must be based upon a discrete and fixed grouping of facts. This court ordered expert reports on dose to be filed by March 1, 1995. Thus, for purposes of this litigation, the discrete body of factual evidence with respect to the issue of dose became fixed on March 1.[55] Accordingly, attempts to build on this body of facts after the filing deadline passed were misplaced. Consequently, the court granted

55. The court has made two exceptions to this deadline based upon extremely compelling circumstances. First, the court allowed Plaintiffs an additional week to view original plant data from the TMI vault. Plaintiffs were permitted to supplement pre-existing expert reports with information drawn from these original plant documents. Second, following Dr. Webb's recantation of the bulk of his "blowout" theory, the court ruled that David Lochbaum could file a new expert report speaking to the "blowout" issue. Despite its strong reservations, the court permitted this additional filing based upon the importance of this theory to Plaintiffs' case and due to the rather bizarre circumstances of Dr. Webb's sudden recantation.

Defendants' motion in limine with respect to all expert reports filed after the deadline for filing such reports.

B. Experts Testifying Regarding the Reports of Others

In ¶ 2 of its November 9 order, the court ruled that no expert could testify as to the substance of the report of a non-testifying expert.[56] Plaintiffs had envisioned that Professor Armentrout would testify as to Professor Neuwirth's soil sample analysis and that Professor Shevchenko would testify as to a barrage of studies conducted by six other Russian scientists. The court found several problems with Plaintiffs' proposed approach. First, neither Professor Armentrout nor Professor Shevchenko were qualified to testify as experts in the fields the subject of the secondary reports. In fact, Professor Armentrout had enlisted the assistance of Professor Neuwirth because he was unable to perform the soil extraction technique on his own. This lack of expertise fed directly into a second problem. Because the testifying experts were not in fact experts, they could not speak intelligently as to the methodology and scientific underpinnings of the secondary reports. This, in turn,

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56. At this juncture, the court's ruling applies only to Professors Shevchenko and Armentrout. The court wishes to make clear, however, that the reach of this ruling extends to all expert scientific testimony whether the testimony is from Plaintiffs' or Defendants' experts. Additionally, the court notes that it has made an exception to its rule with respect to the report of Dr. Snigiryova. The court allowed Professor Shevchenko to testify to this report because it was in his area of expertise. Consequently, Defendants were offered a meaningful opportunity for cross- examination. See DeLuca v. Merrell Dow Pharmaceuticals, Inc., 911 F.2d 941, 953 (3d Cir.1990).

frustrated Defendants' ability to effectively cross-examine as to the secondary reports.

Based upon the foregoing, a reasonable compromise was made. All of the secondary reports had been filed in conjunction with either the Armentrout or Shevchenko reports. As such, there was no element of surprise or lack of notice, because Defendants were in possession of these reports. The court ruled that it would permit testimony on the secondary reports, but only if that testimony was provided by the author of the report. Thus, insofar as Plaintiffs were able to produce these "secondary" experts for the in limine hearings, the "secondary" reports were admissible. Execution of the court's order was frustrated by the federal budgeting impasse ongoing during a portion of the in limine hearings. The partial government shutdown attendant to the impasse included the closing of all passport offices. As a consequence, Dr. Tarasenko was unable to obtain a visa to attend the hearings. The court and the parties agreed that Dr. Tarasenko would be made available as soon as she could obtain a visa.

XIV. CONCLUSION

Based upon the preceding analyses, the court will grant in part Defendants' motion in limine and exclude the proffered testimony of Richard Webb, David A. Lochbaum, Charles E. Armentrout, Victor Neuwirth, James E. Gunckel, Douglas Crawford-Brown, Steven Wing with respect to his mortality study, and a portion of the testimony of Ignaz Vergeiner. The court will deny the motion in part and admit the testimony of Vladimir I. Shevchenko. Finally, the court will defer its ruling as to: the proffered testimony of Dr.

Tarasenko; the new Lochbaum report; the admissibility of the Wing cancer incidence study pending further briefing on the rate of error issue; and, will defer its ruling as to the Molholt corollary hypotheses proffer until the conclusion of the February in limine hearings, provided that Plaintiffs produce Dr. Molholt to testify at those hearings. The court will issue its ruling with respect to the Kozubov proffer on January 8, 1995.

With respect to other pre-trial matters, the court is aware of outstanding issues relating to Plaintiffs' motion to compel certain discovery, and Defendants recent motion to compel production of Plaintiffs' expert reports on punitive damages. Mindful of the need to have consideration of these matters expedited due to the relative proximity to trial, the court expects to rule on these motions promptly.

Finally, the court feels compelled to note a few observations in closing. Throughout the long and arduous history of this litigation, the court has endeavored above all else to be fair, and to provide Plaintiffs with an opportunity to have their day in court. The court is mindful of the blow that has been dealt to Plaintiffs' case through today's ruling. That being said, the court's supreme responsibility is to apply the law in a just and impartial manner. Supreme Court and Third Circuit precedent on the issue of expert scientific testimony is clear. Moreover, this court has made every effort to apprise the parties not only of factors that it deemed especially relevant with respect to its analysis, but also, to put the parties on notice before the hearings as to areas of proffered testimony that were of particular concern to the court. (Tr. at 2-60 (pre-hearing conference). It was Plaintiffs

who carried the burden within this proceeding to demonstrate by a preponderance of the evidence, in light of existing law and the detailed "road map" provided by this court, that the proffered testimony of their experts was scientifically valid and reliable, and based upon good grounds. Unfortunately, for the most part, Plaintiffs were unable to meet this burden and thus must fall victim to rules of evidence "designed not for the exhaustive search for cosmic understanding but for the particularized resolution of legal disputes." Daubert, 509 U.S. at __, 113 S.Ct. at 2798.

An appropriate order will be issued.

APPENDIX H — MEMORANDUM AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF PENNSYLVANIA DATED JANUARY 10, 1996

In re TMI LITIGATION CASES
CONSOLIDATED II.
This Document Relates to All Plaintiffs.

Civil Action No. 1:CV-88-1452.

United States District Court,
M.D. Pennsylvania.

Jan. 10, 1996.

* * *

MEMORANDUM AND ORDER

RAMBO, Chief Judge.

On January 5, 1996, this court filed a lengthy opinion ruling on the bulk of Defendants' pending motion in limine to exclude Plaintiffs' expert testimony on dose. In that order, the court indicated that it would be filing its opinion with respect to Dr. Gennady Kozubov on January 8, 1996. The court was closed on January 8 due to a blizzard which paralyzed much of the east coast. The court will now rule on the admissibility of the proffered testimony of Dr. Kozubov. For a discussion of the factual and legal background of this memorandum, the parties should refer to this court's January 5, 1996 order. In re TMI, No. 88-1452, 1996 WL 12079 (M.D.Pa. January 5, 1996) (memorandum of law

accompanying order granting in part Defendants' motion in limine). The court will proceed with its Daubert/Paoli II analysis.

I. DAUBERT/PAOLI II ANALYSIS

A. Is the Methodology Based Upon a Testable Hypothesis?

The court understands Dr. Kozubov's hypothesis to be that trees in the TMI area were exposed to radiation during the TMI accident, and that damage from this exposure can be seen by examining the growth increments (rings) on the trees. Moreover, the Kozubov hypothesis includes an assumption that a dose can be inferred from the information obtained by examining the trees growth rings. At the hearing, Dr. Kozubov testified that his methodology, referred to as a "dendrometric analysis," had been patented in the former Soviet Union. To obtain a patent, Dr. Kozubov had to subject the methodology to rather rigorous review. (See Tr. at 1437.) Accordingly, the court finds that this factor weighs in favor of admitting the proffered testimony.

B. Has the Methodology Been Subject to Peer Review?

At the hearing, Dr. Kozubov testified that his methodology had been discussed in two peer reviewed articles and that the methodology had been presented at two international conferences. (Tr. at 1437.) Defendants do not appear to dispute the contention that the methodology has been subject to at least minimal levels of peer review. This factor will weigh in favor of the admission of the proffered testimony.

C. Were There Standards Controlling the Technique's Operation?

According to Dr. Kozubov, "[t]here are international standard operating procedures. . . . [and there are] national standards as far as dendrometric measurements are concerned. The standards define the methods of sample preparations, sample retrievals and sample analysis." (Tr. at 1438.) Defendants express concern that despite the existence of standards, the standards might not have been properly followed. Specifically, Defendants note that Dr. Kozubov did not give Professor Shevchenko specific instructions about how to select control trees. Further, it is unknown whether the control trees were taken from the same "urban" environment as the study trees. Finally, Defendants argue that Dr. Kozubov used weather information from the Harrisburg area and applied it to the control group of trees. The control group was located over seventy miles from Harrisburg. (2/17/95 Kozubov Rpt. at 6.) Testimony was presented at the hearing that weather conditions, among other things, would affect the growing patterns of trees. (Tr. at 1448-49; see McClenahen Rpt. at 2.) Thus, Defendants contend that by applying the Harrisburg weather data to the control group, Dr. Kozubov is failing to account for growth discrepancies that may be due to differing weather patterns in the area where the control group is located.

The court is satisfied that while Dr. Kozubov might not have used every standard possible to control the operation of his technique, he did employ proper standards. Thus, although the court finds Defendants' arguments to have a degree of merit, this factor will not weigh against the admission of the proffered testimony.

Appendix H

D. Is the Methodology Generally Accepted

In his testimony, Dr. Kozubov was unable to characterize his methodology as generally accepted. His response to questioning on this subject was as follows:

> Because the patent was received at the end of 1993, I cannot say that this method was tested worldwide. Plus, I have to say that fortunately, thank God, we didn't have enough places, locations in the world where we could test this method. There are only three or four sites worldwide where this methodology can be tested. So probably the term world acceptance, worldwide acceptance, would be the wrong one to use here. The Three Mile Island area is probably only the second location where we're trying and using this methodology.

(Tr. at 1438.) Based upon Dr. Kozubov's testimony, the court finds that the dendrometric methodology is not generally accepted. The court, however, will not weigh this factor heavily against the admission of the proffered testimony. As Dr. Kozubov has indicated, it is likely that the methodology lacks general acceptance more because of the paucity of nuclear disaster sites worldwide than because the methodology lacks merit.

E. Is There a Relationship Between the Technique and Methods that are Established to be Reliable?

Dr. Kozubov testified that there are no established techniques in this particular area of dendrometric analysis.

(Tr. at 1440.) Rather, it is the court's understanding that Dr. Kozubov is pioneering a novel scientific technique. This factor will weigh against the admission of the proffered testimony insofar as the novelty of the technique somewhat diminishes its reliability. However, the unique facts with which the court is dealing dictate that this factor not weigh heavily against admission. Indeed, the court feels uncomfortable finding that more nuclear accidents must occur so that an established and reliable methodology can be developed.

F. Qualifications of the Expert Based Upon the Methodology

No challenge has been made regarding the credentials of Dr. Kozubov. A review of his curriculum vitae indicates that he is amply qualified to testify as to the proffered methodology. This factor will weigh in favor of the admission of the proffered testimony.

G. Non-Judicial Uses

The methodology utilized by Dr. Kozubov was developed in the wake of the Chernobyl accident. This is the first time that the methodology has been proffered for use in litigation. In fact, Dr. Kozubov testified that he became upset when he learned that the TMI study he conducted would be ~~used for~~ litigation. (Tr. at 1462.) The court finds that this factor weighs in favor of the admission of the proffered testimony. That Dr. Kozubov thought that he was performing the study solely for scientific purposes speaks highly of the integrity of the study.

Appendix H

H. Conclusion

The Daubert/Paoli II factors weigh in favor of admitting the proffered testimony. Accordingly, the court will proceed with its Daubert analysis pursuant to Rule 702.

II. Rule 702 "Fit"

The touchstone of the Rule 702 analysis is helpfulness to the trier of fact. In the context of the Daubert analysis, the court must consider whether the proffered testimony will assist the jury in evaluating any fact in issue. Thus, to be helpful, the proffered testimony must have a logical connection to a fact in issue — it must "fit." The proffered testimony, to an extent, has a sufficient connection with a fact in issue — namely the dose question — to "fit" within the litigation. However, on cross-examination, Dr. Kozubov revealed an important caveat regarding his dendrometric analysis which bears directly on the reliability of the testimony and the testimony's "fit." Specifically, Dr. Kozubov testified as follows:

> we always say that this method is only used with other methods. One cannot use just one method to give this estimate.
>
> That's why in Chernobyl, we also studied the needle growth, also we studied growth patterns, seeds and also the wilting process of the leading shoots. That's why our estimations had a compound picture. If we use only this one method, of course we will not say that this was caused by exposure.

(Tr. at 1460 (emphasis added).) No evidence has been presented to demonstrate that any of these other study methods were employed. Accordingly, based upon Dr. Kozubov's own statements, the court finds that the dendrometric study, standing alone, cannot speak to the issue of whether the observed tree damage resulted from radiation exposure. As such, the court is unable to envision how the proffered testimony would assist the jury in determining whether or not persons (and trees) in the TMI area at the time of the accident were exposed to radiation. The court finds that the proffered testimony lacks the requisite Rule 702 "fit" with the instant litigation.

Therefore, in accordance with the above memorandum, IT IS HEREBY ORDERED THAT the proffered testimony of Dr. Kozubov and his dendrometric study shall be excluded.

APPENDIX I — ORDER OF THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF PENNSYLVANIA *IN RE: TMI LITIGATION, CONSOLIDATED PROCEEDINGS*, CIVIL NO. 1:CV-88-1452 DATED AND FILED NOVEMBER 9, 1995

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

CIVIL NO. 1:CV-88-1452

IN RE: TMI LITIGATION
CONSOLIDATED PROCEEDINGS

This Document Relates to:
All Plaintiffs

ORDER

The court, pursuant to the guidance provided by *Daubert* and *Paoli*, has chosen to conduct hearings on Defendants' motion *in limine* to exclude Plaintiffs' dose experts. Although neither *Daubert* nor *Paoli* mandate hearings, both decisions and their respective progeny, counsel that it is firmly within the court's discretion to conduct evidentiary hearings if the court deems such hearings necessary. *See Daubert*, 113 S. Ct. 2786, 2795 (1993) (Stating that the court's gatekeeping role "entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue. *We are confident that federal judges possess the capacity to undertake this review.*" (emphasis added)); *Borawick v. Shay*, 1995 WL 613932 *12 (2d Cir. October 17, 1995) ("[W]e

believe that it would have been more appropriate for the district judge to have conducted an evidentiary hearing prior to issuing his ruling [on the *in limine* issues]."); *Paoli II*, 35 F.3d 717, 735-40 (3d Cir. 1994) ("In *Paoli I*, this Court reversed the Rule 703 holdings because the district court had not created a sufficiently detailed factual record on which to base them . . . . [On remand] [w]e strongly suggested that the district court should have held an *in limine* hearing before excluding Plaintiffs' expert opinion."). An initial review of the voluminous "in limine" evidence before the court leaves the court with questions that must be answered on the record before the court can make an informed ruling on the *in limine* motion.

To promote economy, and to make the hearings most beneficial to the court, it is prudent at this juncture to apprise the parties of factors that will be relevant to the court's final determination. The court prefaces this discussion by noting that this listing of factors is not necessarily exhaustive, and that it is flexible. Application of these and any other factors that the court deems relevant will be tailored to the proffered testimony of each expert. It is possible that factors relevant to the proffered testimony of one expert will be irrelevant to the evaluation of the proffered testimony of a different expert. In *Paoli II*, the Third Circuit made it "clear that a district court should take into account all of the factors listed by either *Daubert* or *Downing* as well as any others that are relevant." *Paoli II*, 35 F.3d at 742. By now, the parties are intimately familiar with the eight *Daubert/Downing* factors (hereinafter "*Paoli* factors"). As such, the court finds it unnecessary to list them again. Accordingly, the court's discussion will focus on the "other factors" that it may consider.

Appendix I

A recent article in the *Texas Law Review* provides an excellent background for the court's discussion. *See* Bert Black, *et al.*, Science and the Law in the Wake of *Daubert*: A New Search for Scientific Knowledge, 72 Tex. L. Rev. 715 (1994) (hereinafter "Science"). In beginning their discussion, the authors of Science note the following:

> The admonition to concentrate on the fundamental question of whether testimony derives from valid scientific knowledge points in the right direction and should bring legal decisions more in line with the realities of science. To realize this promise, however, courts must discard the old surrogates for understanding science and develop a new analytical framework based on the criteria and quality-control mechanisms that scientists themselves rely on in assessing each others' work.

Science, 72 Tex. L. Rev. at 721. To a large extent, the United States Court of Appeals for the Third Circuit has pioneered the "new analytical framework" referred to in Science. As such, this court is in the advantageous position of having a rather detailed roadmap to guide its course. That being said, the court finds certain suggestions made in Science instructive in assisting to refine the *Paoli* analysis and tailor the analysis to fit the contours of this case. In Science, the authors compile a list of "guideposts for understanding and evaluating scientific claims." Science, 72 Tex. L. Rev. at 781 ("These points do not by themselves constitute an adequate basis for resolving scientific issues, but they do provide guideposts that can help nonscientists develop a sense for how science works in practice and for how scientists themselves evaluate their work.").

Appendix I

Because of the unique factual posture of this case, the court finds some of the Science factors inapposite and unhelpful. The factors that have been and will be taken into consideration are as follows:

> Falsifiability. — Scientific explanations must be capable of falsification; that is, the logical form of a hypothesis must make it amenable to empirical testing. . . [the factor is important enough that] the Supreme Court listed [it] first among its factors.
>
> Logical Consistency. — A valid hypothesis cannot be self-contradictory. . . . [I]t is evident that a hypothesis that contradicts itself is logically ill-formed and cannot be tested.
>
> . . .
>
> Consistency with Accepted Theories. — Scientific knowledge tends to be cumulative and progressive, and a hypothesis that is not consistent with accepted theories should be regarded with great caution, whether or not the hypothesis ultimately proves true. . . . Though the Supreme Court rejected the Frye test, it did retain acceptance as one of the factors to be considered in evaluating science.
>
> . . .
>
> Precision. — Broad generalizations are far more difficult to corroborate than precise

> statements and have little explanatory power. . . . If severe and varied tests are the best indicator of validity, it follows that broad generalization that can account for any possible state of affairs, and thus cannot be empirically tested, are not as good.

Science, 72 Tex. L. Rev. at 783-84. Again, the court must stress that it is not using these factors as a checklist. Failure to meet one *Paoli* factor or one of the Science factors listed above will not *per se* indicate inadmissible evidence. The court, rather, views both sets of factors as a flexible construct from which the court will develop an opinion as to the reliability of the evidence.

Finally, a finding of inadmissibility does not mean that a given scientific opinion is false or wrong, or that it might not someday be proven to be true; rather, it means that at this moment in time the evidence is not sufficiently reliable to be admitted as evidence in a case tried before a jury. As Justice Blackmun insightfully remarked in *Daubert*:

> We recognize that in practice, a gatekeeping role for the judge, no matter how flexible, inevitably on occasion will prevent the jury from learning of authentic insights and innovations. That, nevertheless, is the balance that is struck by Rules of Evidence designed not for the exhaustive search for cosmic understanding but for the particularized resolution of legal disputes.

Daubert, 113 S. Ct. at 2798-99.

Appendix I

The purpose of this order is to guide the parties in their presentation of testimony at the *in limine* hearings. A tremendous amount of information has already been placed on the record. As counsel will agree, a significant portion of that information is dense and technical. Through the hearings, the court does not seek replication of the leagues of information already on the record. Such a hearing would clearly be wasteful of the valuable time of the court and the parties. For the hearings to be productive, testimony must focus on synthesizing the information on the record to explain and demonstrate more clearly to the court why a given piece of proffered testimony is either admissible or inadmissible. Helpful testimony will be presented in light of the factors discussed in this order, will avoid excessive repetition of information on the record where possible, and will refrain counterproductive discourse.

s/ Sylvia H. Rambo
SYLVIA H. RAMBO, Chief Judge
Middle District of Pennsylvania

Dated: November 9, 1995

APPENDIX J — ORDER OF *THE UNITED STATES* DISTRICT COURT FOR THE MIDDLE DISTRICT OF PENNSYLVANIA *IN RE TMI LITIGATION, CASES CONSOLIDATED II*, CIVIL NO. 1:CV-88-1452 DATED AND FILED NOVEMBER 9, 1995

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

CIVIL NO. 1:CV-88-1452

IN RE TMI LITIGATION
CASES CONSOLIDATED II

This Document Relates to:
All Plaintiffs

ORDER

On November 9, 1995, the court conducted a pre-hearing conference with the parties to the captioned action. In light of the need for a prompt ruling by the court, the instant order is being issued without an accompanying memorandum of law. Because the issues ruled upon were discussed at length during the conference, and due to time constraints, the court's rulings are necessarily cursory. A memorandum of law elaborating upon the reasoning behind the rulings will follow at a later date. Accordingly, IT IS HEREBY ORDERED THAT:

1) Defendants' motion *in limine* is GRANTED with respect to the following experts and/or portions of their testimony:

Appendix J

a) Dr. L.N. Smierennyi;

b) Steven Wing is precluded from testifying regarding the "new graphs" filed within Plaintiffs' supplemental filings and discussed at length during the conference; however, to the extent that his testimony is truly rebuttal in nature, Wing will be permitted to testify;

c) Dr. Vergeiner is precluded from testifying regarding the new soil sample studies identified in Plaintiffs' supplemental fillings;

d) The unnamed porcelain insulator experts identified on page 9 of Defendants' reply brief in support of their motions *in limine*;

e) Dr. Ivannovich (L.N.U.);

f) Professor Vasilenko;

g) Ronald Kerman is precluded from testifying as to his affidavit analyzing Dr. Tarasenko's work;

h) Zinovy Reytblatt;

i) The letter reports of Professor Eggar and Professor Scharr;

2) No expert shall be permitted to testify as to the substance of reports filed by other experts; at this juncture, this ruling applies specifically to Plaintiffs' experts

Shevchenko and Armentrout, however, the court reserves the right to apply this ruling to any other expert witness involved in the case as the need arises;

3) To the extent that Plaintiffs wish to produce experts Neuwirth, Tascev, Kozubov, Popov, Portman, and Tarasenko at trial to testify to the information that was to be relayed by Shevchenko and Armentrout, Plaintiffs must produce these experts at the *in limine* hearings scheduled to begin November 13, 1995; moreover, they must be produced early enough in the hearing process that the court and Defendants have sufficient time to probe their proffered testimony;

4) To the extent that Plaintiffs are unable to produce the expert witnesses listed in ¶ 3, above, in a timely manner, Defendants' motion *in limine* is GRANTED as to those witnesses.

s/ Sylvia H. Rambo
SYLVIA H. RAMBO, Chief Judge
Middle District of Pennsylvania

Dated: November 9, 1995

APPENDIX K — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT DENYING PETITION FOR REHEARING *IN RE: TMI LITIGATION/LORI DOLAN, et al.*, Nos. 96-7623, 96-7624 and 96-7625 DATED JANUARY 4, 2000

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

Nos. 96-7623, 96-7624 and 96-7625

IN RE: TMI LITIGATION

LORI DOLAN, JOSEPH GAUGHAN, RONALD WARD, ESTATE OF PEARL HICKERNELL, KENNETH PUTT, ESTATE OF ETHELDA HILT, PAULA OBERCASH, JOLENE PETERSON, ESTATE OF GARY VILLELLA AND ESTATE OF LEO BEAM,

Appellants

SUR PETITION FOR REHEARING

BEFORE: BECKER, *Chief Judge*
SLOVITER, MANSMANN, GREENBERG, SCIRICA, NYGAARD, ALITO, ROTH, McKEE, RENDELL, BARRY *Circuit Judges*, and GREENAWAY, *District Judge**

The petition for rehearing filed by the Appellants in the above-entitled case, having been submitted to the judges who

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* The Honorable Joseph A. Greenaway, Jr., United States District Court Judge for the District of New Jersey, vote is limited to panel rehearing only.

participated in the decision of this court and to all other available circuit judges in regular active service, and no judge who concurred in the decision having asked for rehearing, and a majority of the circuit judges in regular active service not having voted for rehearing by this court en banc, the petition for rehearing is here by **DENIED.**

IT IS SO ORDERED.

By the Court,

s/ Theodore A. McKee
Hon. Theodore A. McKee
Circuit Judge

DATED: JAN 04 2000

APPENDIX L - ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT DENYING PETITION FOR REHEARING *IN RE: TMI LITIGATION/ALL PLAINTIFFS EXCEPT LORI DOLAN, et al.*, No. 96-7624 DATED JANUARY 4, 2000

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 96-7624

IN RE: TMI LITIGATION

ALL PLAINTIFFS EXCEPT LORI DOLAN, JOSEPH GAUGHAN, RONALD WARD, ESTATE OF PEARL HICKERNELL, KENNETH PUTT, ESTATE OF ETHELDA HILT, PAULA OBERCASH. JOLENE PETERSON, ESTATE OF GARY VILLELLA AND ESTATE OF LEO BEAM,

Appellants

SUR PETITION FOR REHEARING

BEFORE: GREENBERG, McKEE, *Circuit Judges* and GREENAWAY, *District Judge**

The petition for rehearing filed by the Appellees in the above-entitled case, having been submitted to the judges who participated in the decision of this court and to all other available circuit judges in regular active service, and no judge

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* The Honorable Joseph A. Greenaway, Jr., United States District Court Judge for the District of New Jersey, vote is limited to panel rehearing only.

who concurred in the decision having asked for rehearing, and a majority of the circuit judges in regular active service not having voted for rehearing by this court en banc, the petition for rehearing is hereby **DENIED.**

IT IS SO ORDERED.

By the Court,

s/ Theodore A. McKee
Hon. Theodore A. McKee
Circuit Judge

DATED: JAN 04 2000

APPENDIX M — NAMES OF PLAINTIFFS

ABRAMS, FRED N
ABRAMS, HENRA H (ESTATE)
ABROMITIS, JOY A
ABROMITIS, MICHAEL (ESTATE)
ADAMS, HENRIETTA B (ESTATE)
ADAMS, JEANETTE M
ADAMS, PATRICIA A
ADAMS, PATRICK R (MINOR)
ADAMS, RAYMOND C (MINOR)
ALBRIGHT, BLANCHE G
ALDER, RUTH E (ESTATE)
ALDRICH, WILLIAM A
ALLEMAN, GERALD C SR
ALMONEY, BYRON L
ALMONEY, GEORGIA S
ALMONEY, KYLE M (MINOR)
ALTIGIERI, DENISE J
ALTIGIERI, VICTOR J
ALTLAND, GARY E
ALTLAND, KIMBERLY A (MINOR)
ALTLAND, MELISSA A (MINOR)
ALTLAND, MIRIAM E
ANDERSON, ANNABELLE S
ANDERSON, CARL
ANDERSON, GEORGE W
ANDERSON, GERALDYNE F
ANDERSON, GILBERT C
ANDERSON, PATRICK JR (ESTATE)
ANDERSON, PEARL E
ANGELI, JOHANNA
ANTHONY, DONALD S
ANTHONY, MARIAN (ESTATE)

Appendix M

APPLE, BETTY
APPLE, DORIS J
APPLE, EDWARD R
APPLE, NATHAN D
APPLEBY, SALLIE J
ARMSTRONG, JOAN M
ARMSTRONG, JOHN F
ARMSTRONG, MILES C JR
ARMSTRONG, SYBIL (MINOR)
ARMSTRONG, WALTER O
ARNDT, EDWARD P JR
ARNDT, KATHY J
ARNOLD, DORIS J
ARNOLD, RODNEY C
AUCKER, JAYNE L
AUNGST, BEN (MINOR)
AUSTIN, JOHN E
AUSTIN, JUANITA F (ESTATE)
BAIR, JUDITH G (ESTATE)
BAIR, RONALD A
BAKARIC, NICHOLAS G
BAKER, H RICHARD
BAKER, MARGARET V (ESTATE)
BALCHUNAS, KAY L
BALCHUNAS, RALPH E
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No. 99-1603

IN THE

Supreme Court of the United States

GENERAL PUBLIC UTILITIES CORP., *et al.*,

Petitioners,

v.

FRED N. ABRAMS, *et al.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF IN OPPOSITION FOR ALL PERSONAL INJURY RESPONDENTS

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STATEMENT OF THE CASE

The case described and argued by Petitioners in their Petition for Writ of Certiorari misrepresents the case and facts presented to the Third Circuit Court of Appeals and the United States District Court for the Middle District of Pennsylvania. Respondents are nearly 2,000 plaintiffs who filed personal injury and loss of consortium claims arising out of the nuclear plant accident that occurred at Unit 2 at Three Mile Island ("TMI") on March 28, 1979. They filed their cases over the course of time ranging from 1985 to as late as March 15, 1996 in different courts, through multiple complaints. Their cases were instituted in state and federal courts in Mississippi, as well as in state and federal courts in Pennsylvania. Their cases were never considered for class action certification pursuant to Federal Rule of Civil Procedure 23. In fact, a motion for class certification of a TMI personal injury case that was instituted in 1979 (and which is unrelated to the present cases pending before the Court) was denied at the insistence of the instant Petitioners on the basis of their argument that individual questions predominated over the common questions. *See In re Three Mile Island Litigation*, 87 F.R.D. 433, 440-442 (M.D. Pa. 1980).

Respondents who filed cases before August 20, 1988 expected to litigate their claims in the various forums where they were filed. However, the Price-Anderson Act was amended in 1988, 42 U.S.C. §§ 2014(hh), 2210(n)(2) allowing for the transfer and removal of all cases involving the Three Mile Island accident to the United States District Court for the Middle District of Pennsylvania. *See In re TMI Litigation Cases Consolidated II*, 940 F.2d 832 (3d Cir. 1991), *cert. denied sub nom., Gumby v. General Public*

Utilities Corp., 503 U.S. 906 (1992) (sustaining retroactive creation of federal jurisdiction for "public liability actions"). Once the constitutionality of the 1988 Amendments was determined, the district court approved a stipulation of the parties to accomplish an "administrative" consolidation of the cases into a master docket. The approved stipulation provided in part as follows:

> 1. All actions and causes of action in the civil actions . . . shall be consolidated for *administrative purposes* in one civil action, being Civil Action No. 1:88-1452
>
> * * *
>
> 3. Nothing in paragraphs 1 or 2 of the Stipulation or the dismissals pursuant thereto shall be deemed to constitute or affect any waiver of any claim, defense or issue, including but not limited to the statute of limitations, choice of law and bifurcation or consolidation for trial of claims, defenses, issues, parties or proceedings. (emphasis added).

Accordingly, the parties stipulated that the cases would be consolidated for *administrative purposes* only. The stipulation did not say anything about consolidating discovery for all plaintiffs, consolidation as to certain or predominating issues (the stipulation does not even identify any issue that is common, let alone one that is predominating), or the intent to conduct a consolidated trial or pretrial proceedings that would be binding on all plaintiffs. The consolidation was limited in nature, with a reservation of rights that plainly provided *inter alia*, that "claims, defenses, issues, parties or proceedings" would not be affected by the consolidation.

Subsequent to the administrative consolidation of the cases, the district court solicited case management proposals from the parties. Respondents proposed that a group of bellwether-like, test-case plaintiffs be selected, whose cases would be fully litigated in the expectation that the results of the litigation of those cases could "yield a high level of predictive value to the parties and counsel thereby providing a framework for the resolution of the remaining claims without endless repetition of trials." Respondents did not propose that the results of the litigation of the selected bellwether plaintiffs would bind the thousands of remaining plaintiffs in the litigation. The point of Respondents' proposal was to provide a basis by which the parties and the district court could *possibly* assess the values for a cross-section of claims, and also provide a basis for determining what kind of framework might be suitable for resolving the claims of the remaining non-bellwether plaintiffs.

Respondents modeled their proposal after the bellwether approach adopted in another radiation exposure case, *Allen v. United States*, 588 F. Supp. 247 (D. Utah 1984), *reversed on other grounds*, 816 F.2d 1417 (10th Cir. 1987), *cert denied*, 484 U.S. 1004 (1988), and quoted the *Allen* court case management plan as follows:

> This action is a consolidation of the individual claims of the 1,192 named plaintiffs. This is not a class action. . . . The trial encompassed 24 of the claims in their entirety. Pursuant to the suggestion of the court, these cases were selected by plaintiffs' and defendant's counsel as "bellwether" cases. The effort was to provide a selection of "typical" cases which when decided and reviewed may provide a legal and factual

> pattern against which the remaining issues in the pending cases may be subsequently matched.

Allen, 588 F. Supp. at 258.

Respondents' proposal also relied upon other case management plans that utilized the bellwether approach, where the merits of the selected bellwether cases only were at issue. *See, e.g., Cimino v. Raymark Industries, Inc.*, 739 F. Supp. 328, 329-30 (E.D. Tex. 1990), *reversed and remanded in part*, 151 F.3d 297 (5th Cir. 1998). In fact, one of Respondents' counsel had successfully utilized such a bellwether case management plan in the litigation of another mass tort case, that resulted in the settlement of all of the claims after the trial of the several bellwether plaintiffs' claims provided cross-sectional predictive value for the non-selected claims. Respondents relied on their counsel's citation[1] of that experience in requesting the TMI district court to adopt a bellwether approach.

Petitioners disagreed with Respondents' suggestion that the adoption of a bellwether approach would be useful. *Petitioners themselves acknowledged and argued that such*

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1. One of Respondents' counsel was lead counsel in a mass tort case involving the dioxin contamination of the Times Beach, Missouri community. Bellwether plaintiffs were selected for a trial in that case. After that trial, the remaining cases were resolved. Respondents' counsel provided a copy of the slip opinion to the TMI district court regarding the dioxin case experience which stated that "the theory is that such approach will give the parties a reasonable appraisal of the value of the remaining claims and result in settling them." *See Akers, et al. v. Syntex Agribusiness, et al.*, Cause No. 842-04887, etc. (Circuit Court of the City of St. Louis, State of Missouri) (slip opinion February 7, 1989).

an approach would not and could not have any binding effect on the thousands of remaining claims that would remain on the sidelines pending resolution of the bellwether claims. Petitioners argued that "[T]he 'test case' approach does not portend to resolve anything except the test cases selected." In other words, Petitioners acknowledged that the litigation of bellwether claims would not and could not be binding on the claims of the other plaintiffs, absent an agreement by the non-bellwether plaintiffs to that effect. No such agreement was ever reached, and clearly, Respondents' state of mind was that their claims would not be at issue during the litigation of the bellwether cases. Just as Petitioners recognized, Respondents believed their cases remained on the sideline during the litigation of the bellwether cases.

The district court rejected Petitioners' objection to the Respondents' case management proposal. The district court adopted Respondents' case management proposal with an acknowledgment that plaintiff-specific inquiries existed that would likely vary greatly among the many plaintiffs that would require *individual* consideration of each plaintiff's claim, and that the need for such individual consideration of each case precluded the adoption of a case management plan that would be akin to a class certification.

The district court adopted Respondents' case management plan *without modification or qualification*. That plan simply placed the claims of the selected bellwether plaintiffs at issue, without having any binding effect on the non-selected Respondents. Thereafter, as the discovery relevant to the claims of the bellwether plaintiffs was conducted, there was never any specific mention of the claims of the non-selected Respondents. There was no development of any particular facts relating to the claims of the 2,000

Respondents, as virtually none of them were deposed (other than a small number of same for the *limited* purpose of allowing the parties to make their selections of the bellwether plaintiffs) and limited documentary evidence was obtained with respect to any of them. The litigation was then conducted precisely the way envisioned by all plaintiffs, *i.e.*, the claims of bellwether plaintiffs were developed and discovered, utilizing their specific legal, factual and scientific theories that they chose to be applicable to their cases, with the claims of the remaining 2,000 plaintiffs' essentially stayed pending the outcome of the bellwether cases. And, contrary to Petitioners' contention, this is a fact, and not a misconceived perception held by Respondents.

Logically, Petitioners were as unwilling as the Respondents to concede that whatever was resolved in the litigation of the bellwether cases would also be binding against Petitioners or Respondents, for all cases. All parties wanted to reserve their rights on each and every claim. And, in the face of Petitioners' prior opposition to the class certification of a personal injury class, it was certainly reasonable to believe Petitioners themselves were not conceding a right to challenge each plaintiff's claim. During the course of all of the pretrial proceedings, no suggestion was ever made by Petitioners that the administrative consolidation of the cases in fact affected a substantive consolidation that would affect the rights of the non-bellwether plaintiffs.

Upon the conclusion of the pretrial proceedings involving the 10 bellwether plaintiffs' cases, Petitioners made an extensive attack pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) ("*Daubert*") on the admissibility of their expert evidence. The *Daubert* proceedings were fierce, and the outcome was far from certain.

However, once the district court made its *Daubert* exclusion rulings in favor of Petitioners with respect to the expert evidence proffered by the 10 bellwether plaintiffs[2] (which evidence Respondents would have sought to adopt subject to collateral estoppel and *res judicata* principles against Petitioners, but without a waiver to proffer additional evidence), Petitioners moved for summary judgment against the 10 bellwether plaintiffs. In a *footnote* to their memorandum in support of that motion, Petitioners suggested, almost as an afterthought, that if the district court were to grant summary judgment against the 10 bellwether plaintiffs, it could do so as to all of the remaining 2,000 plaintiffs' claims in the litigation. The footnote was the first time in the litigation that anyone had suggested that anything beyond the cases of the 10 bellwether plaintiffs were at issue under the terms of the case management plan proffered by the plaintiffs and adopted by the district court.

And, it certainly made sense that Petitioners would never have raised this absurd proposition any time earlier in the litigation of the 10 bellwether claims, because Petitioners

2. The 10 bellwether plaintiffs are the Petitioners in No. 99-1604 before the Court, wherein they seek review of the *Daubert* proceedings and rulings that resulted in the exclusion of the majority of those plaintiffs' expert evidence and the entry of summary judgment against them that was extended to Respondents. It is noteworthy that no TMI personal injury case has ever been tried, even after the passage of over 21 years since the accident occurred, not so much because of a rash of settlements, but because of the relentless maneuverings by Petitioners that have kept the cases tied up in legal procedural hurdles, and appeals. *See, e.g., In re TMI*, 193 F.3d 613, 623-29 (3d Cir. 1999) (discussing some of the procedural history of TMI litigation) [J. App. 12a-25a]. (Since the 10 bellwether plaintiffs also filed a Petition for a Writ of Certiorari, at No. 99-1604,a separate bound joint appendix ("J. App.") has been filed.)

wanted to preserve their right to argue that nothing that was litigated in those 10 cases would or could be binding against Petitioners with respect to the claims of the non-bellwether Respondents. Indeed, this type of protective philosophy has been the hallmark driving force behind most mass tort defendants' actions in opposing class certifications of personal injury cases, including even the certification of an "issues" class pursuant to Federal Rule of Civil Procedure 23(c)(4)(A). Obviously, Petitioners wanted to "hedge" against a *Daubert* ruling that might have gone against them to preserve an opportunity to argue that the evidence that may have been admitted against them in the bellwether cases was not *res judicata* against them as to the claims of the non-bellwether plaintiffs.

The *Daubert* exclusion rulings gave Petitioners the comfort and security they needed to take the bold step to argue that in spite of the limited nature of the administrative consolidation of the cases, all plaintiffs were now bound by the rulings in the bellwether cases. It certainly would be interesting to know whether Petitioners would have taken such a bold step if the *Daubert* rulings had gone against them, and whether they would have conceded that all plaintiffs were entitled to the benefits of such rulings. Respondents do not believe Petitioners would have agreed to such a result had the tables been turned, and their argument in support of summary judgment against all plaintiffs demonstrates a lack of candor, which the Third Circuit recognized.

Nevertheless, once the *Daubert* rulings went in favor of Petitioners, they cleverly proposed to the district court not only that all of the pretrial proceedings that had occurred in the 10 bellwether cases were always understood by all parties to be binding on all plaintiffs, but also that no plaintiff could

proffer any evidence, or legal or scientific theory, to support a case beyond the evidence and theories that was in the record for the cases of the 10 bellwether plaintiffs.

All plaintiffs opposed the motion for summary judgment. Specifically, Respondents made numerous arguments as to why summary judgment could not be entered against them, regardless of the state of the record with respect to the 10 bellwether plaintiffs. In summary, Respondents argued that the record established that only the 10 bellwether cases were at risk during the course of the pretrial proceedings, and that an *administrative* consolidation order could not affect the substantive rights of plaintiffs whose cases were not being actively litigated. Respondents argued that they had the right to present different proofs, experts and theories from those presented by the bellwether plaintiffs, and that this right was never waived and that no notice, such as a notice that would be equivalent to one that would be provided pursuant to Federal Rule of Civil Procedure 23, was ever given to Respondents to alert them that their rights were at risk by reason of an "administrative" consolidation. Further, Respondents argued that they were not bound by collateral estoppel principles to the proofs, theories and experts of the bellwether plaintiffs.

In essence, Respondents argued that because personal injury litigation involves highly individualized questions, including *inter alia*, the question of causation, each plaintiff is entitled to the development of the specific facts pertinent to each plaintiff's situation as part of the pretrial proceedings relating to each plaintiff's case. Plaintiffs argued that their claims could not be foreclosed by determinations made by the district court in litigation involving the claims of the 10 bellwether plaintiffs only.

In spite of Respondents' arguments, the district court fell victim to Petitioners' clever recharacterization of the scope and reach of the proceedings on the bellwether cases, and determined to extend its summary judgment determination against the 10 bellwether plaintiffs to the Respondents. In fact, the district court extended its summary judgment even to cases that had been consolidated as recently as only weeks after the filing of a complaint.[3]

On appeal to the Third Circuit, Respondents argued that summary judgment as to them had to be reversed because of numerous district court errors, including, *inter alia*: (1) its use of Federal Rule of Civil Procedure 42(a) to accomplish the equivalent of a class certification where no class had been certified and no notice had issued; (2) applying the equivalent of the doctrine of collateral estoppel to bar the claims of all of the non-bellwether plaintiffs where virtually no discovery had been taken in any of the cases, and none of those cases had any record upon which to access whether or not a genuine issue of material fact existed; (3) holding that defendants met their burden of establishing the existence of sufficient record evidence as to each of the non-bellwether plaintiffs' individual causation issues, where in fact no case specific evidence was developed by either party with respect

3. A group of plaintiffs filed a complaint on March 15, 1996. That case was "administratively" consolidated into the so-called master docket by the district court's Order entered on March 25, 1996. Petitioners answered the complaint on May 21, 1996 and these plaintiffs suffered summary judgment along with all other non-bellwether plaintiffs on June 7, 1996, 17 days later. The summary judgment occurred without any case specific litigation occurring. The entry of that summary judgment demonstrates the district court's sweeping interpretation of the administrative consolidation order, without any regard for the substantive rights of the plaintiffs, or the status of the record in any particular case.

to same, because the bellwether case management approach to the litigation did not result in the development of any case specific evidence for the non-bellwether plaintiffs' cases; and (4) that the non-bellwether plaintiffs were deprived of an opportunity to pursue their litigation through the development of their own evidence and scientific and legal theories. In essence, Respondents argued that their Seventh Amendment rights were denied.

The Third Circuit agreed that Respondents improperly suffered summary judgment and accordingly reversed the same. *In re TMI*, 193 F.3d at 723-727. [J. App. 257a-268a] The Third Circuit also rejected Petitioners' request for rehearing. [J. App. 682a-683a]

The Third Circuit determined that the primary inquiry should be on what effect an administrative consolidation of cases can have on the substantive rights of parties in a consolidated case. The Third Circuit noted that consolidation is only a matter of "convenience and economy in administration", citing *Johnson v. Manhattan R. Co.*, 289 U.S. 479, 497 (1933), and that "[c]onsolidation 'does not merge the suits into a single cause or change the rights of the parties, or make those who are parties in one suit parties in another'." *In Re TMI Litigation*, 193 F.3d 613, 724 (3d Cir. 1999). [J. App. 260a] The Third Circuit further concluded that a district court cannot properly extinguish substantive rights of plaintiffs merely because all of the cases had been consolidated. The Third Circuit recognized that a "test plaintiff" (*i.e.*, a bellwether) approach to a mass tort case preserves the rights of the non-participating, non-bellwether plaintiffs, whose claims are truly not at issue during the pretrial litigation of the claims of the bellwether plaintiffs. Further, the Third Circuit relied upon Federal Rule

of Civil Procedure 42(b), and emphasized the preservation of the right of trial by jury. *Id.* at 725. [J. App. 263a]

Finally, the Third Circuit also concluded that the extension of summary judgment to the claims of the non-bellwether plaintiffs improperly extended the doctrine of collateral estoppel/issue preclusion, citing *DeLuca v. Merrill Dow Pharmaceuticals, Inc.*, 911 F.2d 941 (3d Cir. 1990) for the proposition that:

> [W]e do not have the authority to create special rules to address the problems posed by continued Bendectin litigation. Principles of issue preclusion have not developed to the point where we may bind plaintiffs by the finding of previous proceedings in which they were not parties, even by a proceeding as thorough as the multidistrict common issues trial. *Id.* at 952.

Id. at 726. [J. App. 264a-265a]

Thus, the facts recited by Petitioners are incomplete and misrepresent the state of the record in at least the following respects:

1. Petitioners imply that the trial court consolidation consolidated all plaintiffs' claims for all purposes, and drew bright line deadlines for the completion of all fact and expert discovery for all plaintiffs' cases. *See* Petition at Question Presented, and at 4, ¶4. This is untrue and misleading, in that virtually no facts were developed for any of the non-bellwether plaintiffs' cases, and no case specific expert evidence was submitted by either *Petitioners* or Respondents relative to the individual issues relating to the causation of

their personal injures. This is so, because during the pretrial litigation of the bellwether cases, before the *Daubert* rulings, Petitioners themselves truly recognized that only the bellwether cases were at issue, and Respondents' cases were essentially stayed.

2. Petitioners' statement that the expert evidence that the district court excluded pursuant to its *Daubert* rulings defined and delimited the extent of any expert evidence and legal and scientific theories that could be pursued by the non-bellwether plaintiffs is wrong. *See* Petition at Question Presented, and at 5. While the non-bellwether plaintiffs certainly would have sought to take advantage of the expert evidence proffered by the bellwether plaintiffs, they neither consented to nor agreed that the scope of the expert evidence upon which they could or would rely was limited to the expert evidence and the legal and scientific theories being pursued by the bellwether plaintiffs.

3. Petitioners' statement that the stipulation of counsel for the dismissal of the multiplicity of different civil actions affected an agreement that every plaintiff in every action was thereafter to be treated as a plaintiff in one consolidated action for substantive purposes is wrong. *See* Petition at 4, ¶2. This statement incorrectly implies that the non-bellwether plaintiffs agreed that their substantive rights would be affected by the consolidation. However, they never expressed any agreement that the litigation of the individual bellwether claims would be binding on them.

4. Petitioners' argument that the protocol that was allegedly established to differentiate between pleadings applicable to all plaintiffs, and pleadings applicable to just a few plaintiffs, demonstrated a conscious willingness on the

part of the Respondents to waive their individual rights, is misleading. *See* Petition at 4, ¶3. The protocol was not uniformly followed by either of the parties or by the district court. In other words, there were instances where an "All Plaintiff" caption was used where the substance of the pleading clearly applied to only one or several plaintiffs, but not all. In any event, substantive rights cannot be extinguished simply by a form over substance argument that works to the severe detriment to the substantive rights of the non-bellwether plaintiffs.

5. The statement that the district court established deadlines applicable to all plaintiffs for discovery, including the submission of expert reports pursuant to Federal Rule of Civil Procedure 26(a)(2), is wrong. *See* Petition at 4, ¶4. No deadlines at all were established to govern any of the discovery for the non-bellwether plaintiffs, and in fact, no discovery and no causation reports for the non-bellwether plaintiffs were submitted by *either* party during the course of the pretrial litigation of the bellwether plaintiffs' cases.

6. Petitioners' statement that the district court in effect "severed" for trial the claims of the bellwether plaintiffs while in all other respects the litigation proceeded as a single consolidated case is untrue. *See* Petition at 4, ¶5. No order of severance was ever entered, and no order was ever entered that amended the order accomplishing the *administrative* consolidation of the cases so as to place the non-bellwether plaintiffs on notice that their substantive rights might be impacted by the proceedings involving the bellwether cases. Indeed, there was no concurrent litigation of the non-bellwether cases while the bellwether cases were being prepared for trial. The non-bellwether cases were left on the sideline by all parties, consistent with the true scope, purpose

and meaning of the administrative consolidation and plaintiffs' case management plan adopted by the district court.

7. Petitioners unfairly imply that *all* plaintiffs adopted a causation theory that the bellwether plaintiffs chose to pursue. (The bellwether plaintiffs presumed they each received a dose of 10 rems or more of radiation, and that such a dose more likely than not caused their cancers or neoplasms.) *See* Petition at 5. This unfairly implies that all plaintiffs accepted the theory that a minimum dose of 10 rems was the threshold needed to establish medical causation in each of their cases. The non-bellwether plaintiffs never acknowledged a minimum 10 rem threshold dose theory and the medical causation expert reports proffered by the 10 bellwether plaintiffs pertained only to the specific cases of the bellwether plaintiffs, the only cases at issue.

8. Petitioners' statement that the causation expert opinions were expressly contingent on proof that each plaintiff had received a dose of 10 rems or more unfairly implies that all non-bellwether plaintiffs accepted a minimum 10 rem dose as a threshold. *Id.* However, none of the causation reports proffered by the bellwether plaintiffs pertained to or even discussed the circumstances of any of the non-bellwether Respondents' claims. In fact, even Petitioners' causation experts did not specifically address the non-bellwether plaintiffs' claims in their reports. The non-bellwether claims simply were not at issue.

9. Petitioners' statement that Respondents did not interpose an affidavit pursuant to Federal Rule of Civil Procedure 56(f), stating what additional affidavits or discovery Respondents needed to oppose the motion for

summary judgment, is misleading. *Id.* This statement incorrectly presupposes that the non-bellwether plaintiffs were parties to the pretrial proceedings, which they were not. The non-bellwether plaintiffs' claims were not at issue, as their claims were only administratively consolidated. Of equal importance, Petitioners did not proffer any plaintiff specific expert evidence addressed to any one of the approximately 2,000 non-bellwether plaintiffs' cases to demonstrate that they even had a right to summary judgment against them. No basis for the summary judgment request against the non-bellwether plaintiffs existed in the record. It was nothing more than a fabrication of Petitioners, founded on a recharacterization of the scope and reach of the consolidation, made only after the district court's *Daubert* rulings. Thus, there was no need for a Rule 56(f) affidavit.

* * * *

The true essence of Petitioners' motion for summary judgment was that they were entitled to such relief against the 10 bellwether plaintiffs because the expert evidence proffered by those plaintiffs to establish that each one had been exposed to a minimum dose of 10 rems of radiation or more had essentially been *Daubert* excluded, and that as a result of the exclusion of such evidence, the case specific medical causation reports that they proffered that were premised on an assumption of 10 rem exposure necessarily had to fail for a lack of foundational evidence. However, Petitioners then tried to extend this reasoning to the non-bellwether plaintiffs' claims. But, no record existed in the trial court that establishes that the non-bellwether plaintiffs agreed to a 10 rem threshold burden, and in opposing the "footnote" request for summary judgment, they presented evidence that established the existence of other legal and

scientific theories that would permit their cases to be litigated irrespective of the exclusion of certain expert evidence proffered by the 10 bellwether plaintiffs. For example, the non-bellwether plaintiffs presented evidence that the scientific community recognizes that there is no safe threshold for exposure to radiation and the resulting induction of cancer. In fact, even though the district court rejected that argument, the Third Circuit credited it, in reversing the summary judgment against the Respondents. *See In re TMI*, 193 F.3d at 726-727. [J. App. 265a-268a]

Accordingly, the decision of the Third Circuit to reverse the summary judgment granted by the district court against the non-bellwether plaintiffs was eminently correct. The decision to reverse was well supported by the state of the record and the legal principles that preclude the entry of summary judgment in inappropriate circumstances.

REASONS FOR DENYING THE WRIT

A. The Court Should Not Grant Review Because The Third Circuit's Determination To Reverse The Entry Of Summary Judgment Was Consistent With The Record Below, In Spite Of Petitioners' Attempts To Persuade The Court That A Grave Departure From The Accepted And Usual Course Of Judicial Proceedings Has Occurred

Petitioners strenuously argue that what occurred in the Third Circuit in the nature of the reversal of summary judgment was unique and must not be allowed to stand as precedent that may allow plaintiffs and their counsel to exercise a veto power over the ability of a district court to entertain a summary judgment motion. Petitioners are simply

incorrect that the Third Circuit decision represents any departure from the accepted and usual course of judicial proceedings. All that the Third Circuit did was to reverse an improvidently granted summary judgment that the district court was duped into granting on the basis of Petitioners' clever recharacterization of the status of the record.

Contrary to Petitioners' argument, other courts presiding over mass tort litigation have been careful to recognize the individual nature of personal injury claims. This philosophy derives from the fact that each individual plaintiff has a unique exposure history, and medical and familial background. The presence of that fact has resulted in the frequent determination that individual questions predominate in mass tort personal injury cases. In the absence of a truly predominating and dispositive common issue that possibly could resolve litigation based on a question of law and not on the facts, procedural devices cannot be utilized to deprive plaintiffs of substantive rights.[4]

4. In mass tort litigation, because of the usual absence of a predominating common question, the cases generally are not susceptible to class certification nor resolution on a mass basis, unless a single determinative legal issue, such as preemption is present. *See, e.g., Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) (question of whether independent cause of action preempted by Medical Device Amendments of 1976, 21 U.S.C. § 360(K) — where preemption is found, independent or private cause of action precluded — case therefore capable of determination on basis of question of law without regard to case specific facts). In mass tort personal injury litigation where no single legally determinative issue such as preemption is applicable, the claims of the plaintiffs are driven by their individual facts. In *TMI* litigation, Petitioners lost the only possible issue that may have been legally determinative as to the claims of all plaintiffs, *i.e.*, the question of whether or not they breached their duty of care. *See In re TMI*, 67 F.3d 1103 (3d Cir. 1995), *cert denied*, 516 U.S. 1154 (1996) (holding that defendants had breached their duty of care owed to all plaintiffs).

The petition for writ of certiorari therefore, should not be granted because this case raises no compelling issue that would warrant review by this Court. This is so in spite of Petitioners' attempt to shoehorn the facts of this case into an argument that the Third Circuit's decision "gives plaintiffs' counsel a right to veto the Federal Rules of Civil Procedure, if they choose, [thereby presenting] such a departure from the 'accepted and usual course of judicial proceedings . . . as to call for an exercise of this Court's supervisory power.' S.Ct. R. 10 (a)." Petition at 10. For the most part, Petitioners' asserted reasons for review are based on their misleading and incomplete recitation of the record below and their flawed attempt to demonstrate that the Third Circuit improperly applied settled rules of law to the facts and issues.

Nowhere did the Third Circuit effectively revoke Rule 56, as argued by Petitioners. In fact, the Third Circuit's opinion specifically acknowledges the usefulness of the summary judgment device in appropriate cases. The Third Circuit stated:

> Summary judgment does not violate a party's Seventh Amendment jury trial rights so long as the person having the right to a jury trial is an actual participant in the summary judgment proceeding. *See City of Chanute, Kansas v. Williams Natural Gas Co.*, 955 F.2d 641, 657 (10th Cir. 1992) ("[S]ummary judgment, applied properly, does not violate the Seventh Amendment.") (citing *Fidelity & Deposit Co. v. United States ex rel. Smoot*, 187 U.S. 315, 319-21, 23 S.Ct. 120, 47 L.Ed. 194 (1902)). However, absent a positive manifestation of agreement by

> Non-Trial Plaintiffs, we cannot conclude that their Seventh Amendment right is not compromised by extending a summary judgment against the Trial Plaintiffs to the non-participating, non-trial plaintiff. In fact, a Seventh Amendment argument was made in the district court, but the argument was summarily dismissed. 927 F. Supp. at 838 n. 7.

In re TMI Litigation, 193 F.3d at 725. [J. App. 263a-264a] The spin that Petitioners place on these statements by the Third Circuit, in an attempt to bolster their argument that Rule 56 has been revoked by the Third Circuit opinion, is that summary judgment cannot be entered against a party unless the party expresses positive agreement to submit to the summary judgment proceedings. This is not what the Third Circuit held, and accordingly, no departure from the "accepted and usual course of judicial proceedings" occurred. In fact, the Third Circuit *affirmed* the entry of summary judgment against the bellwether plaintiffs.

The only fair interpretation of the Third Circuit's holding is that summary judgment cannot be entered against a party who is not a participant to the proceedings leading to the summary judgment motion. This proposition is not astonishing. In fact, this is the hallmark for the notice requirement that exists in Federal Rule of Civil Procedure 23. If a party is to be bound by legal proceedings that can potentially affect that party's substantive rights, the party is fairly entitled to know that the proceedings may have that impact, so that the party can adequately protect his or her interests. *See, e.g., Mullane v. Central Hanover Bank & Trust Co.*, 339 U.S. 306 (1950).

The record in this case clearly reflected that the non-bellwether plaintiffs had not been placed on any fair notice that their claims were being litigated at the same time as the litigation of the bellwether cases. No case specific discovery was taken from the non-bellwether plaintiffs, no case specific expert evidence was submitted by *either* party as to those claims, and the cases were essentially stayed awaiting the outcome of the bellwether cases. This is the only fair interpretation of the record below, based on, *inter alia*, the language of the administrative consolidation, the district court's adoption of the plaintiffs' case management plan, and the parties' conduct of the litigation, *i.e.*, with no development of any record relating to the claims of the non-bellwether plaintiffs.

Petitioners' splicing together of tiny pieces of the enormous record in this case, such as the captions of court filings and isolated statements made by counsel, in an effort to create a false impression that each of the nearly 2,000 non-bellwether plaintiffs expressly agreed to be bound by the entirety of the outcome of the bellwether plaintiffs' claims, simply defies the logic of the adoption of a bellwether case management procedure.

B. The Court Should Not Grant Review For The Purpose Of Articulating New Judicial Law That Would Authorize Lower Courts To Compromise Substantive Rights For The Sake Of Decreasing Docket Pressure

Petitioners' last gasp argument in support of Court review is that in the absence of such review, courts will be denied access to the efficiency-enhancing procedural devices that are intended to be available to them for clearing crowded dockets. Petition at 11. However, judicial efficiency cannot

be purchased at the expense of substantive rights. *See Malcolm v. National Gypsum Co.*, 995 F.2d 346, 350 (2d Cir. 1993) ("[t]he benefits of efficiency can never be purchased at the cost of fairness"). *See also Arnold v. Eastern Airline, Inc.*, 712 F.2d 899, 906 (4th Cir. 1983) (*en banc*), *cert denied*, 464 U.S. 1040 (1984); *C. Wright & A. Miller*, Federal Practice & Procedure: Civil 2d § 2383. pp. 440-42 (1995).

Indeed, as noted by the Second Circuit in *In re Brooklyn Navy Yard Asbestos Litigation*, 971 F.2d 831, 853 (2d Cir. 1992), "the systematic urge to aggregate litigation must not be allowed to trump our dedication to individual justice, and we must take care that each individual plaintiff's — and defendant's — cause not be lost in a shadow of a towering mass litigation." Thus, in *Cimino v. Raymark Industries, Inc.*, 151 F.3d at 311-321, the Fifth Circuit discussed at length the burden placed on the courts by mass tort litigation, but held steadfast to protect the Seventh Amendment right. The Fifth Circuit also refused to abridge that right on the basis of a Fed. R. Civ. P. 42(a) consolidation.

Crowded court dockets cannot and should never be the justification for abridging individual substantive rights. Indeed, this Court has twice rejected even class action approaches for the clearing of crowded court dockets of cases arising out of the asbestos mass tort experience. *See Ortiz v. Fibreboard Corp.*, 527 U.S. 815 (1999); *Amchem Products, Inc. v. Windsor*, 521 U.S. 591 (1997).

CONCLUSION

For the reasons given above, the Petition should be denied.

Respectfully submitted,

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IN THE

Supreme Court of the United States

GENERAL PUBLIC UTILITIES CORPORATION, *et al.*,

Petitioners,

v.

FRED N. ABRAMS, *et al.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

REPLY BRIEF

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In their Brief in Opposition, Respondents do not disagree with the legal propositions advanced in the Petition. Instead, in a transparent attempt to position this case as nothing but a messy factual dispute not worthy of this Court's attention, Respondents accuse Petitioners of misrepresenting or distorting the record, and of making untrue or misleading statements in their Petition to this Court. As a result, they say, the question presented does not really arise here. Respondents are wrong, in a way that goes to the heart of the question presented.

If it were true that Respondents were never intended to have been, and never were, participants in any of the fact or expert discovery, or the *in limine* proceedings, or the consequent summary judgment proceedings, but nevertheless had judgment entered against them, then a substantial due process concern would arise. But that is not true. In the words of Respondents' own attorneys, at the time they were attempting to persuade the district court to adopt their suggested "test case" approach to trial:

> Plaintiffs' proposed plan establishes the dates by which various pretrial proceedings shall be completed and schedules a trial date. The schedule proposed by plaintiffs provides the parties with fair and adequate time to: conduct both factual and expert discovery in the case; identify the plaintiffs whose claims will be tried in the first trial; narrow the issues by way of filing dispositive motions. . . .

Plaintiffs' Memorandum Regarding Plaintiffs' Case Management Plan, at 1. Since the schedule accompanying the plan contemplated that much of the time allotted for discovery would occur *before* the "test cases" for trial were even selected, perforce that discovery was not limited to discovery by or against only the plaintiffs selected for the initial trial.

That same Memorandum Regarding Plaintiffs' Case Management Plan also reflected the understanding of Respondents' attorneys that the cases were not consolidated solely for "administrative purposes," as they now assert, but rather for pretrial proceedings, as the Petition asserts. Respondents' attorneys there wrote (at 3):

> Plaintiffs understand that the reason why *this Court consolidated the instant cases for coordinated pretrial proceedings* was to establish a mechanism by which a fair resolution *of all these cases* can be reached in an expeditious manner.

(Emphasis added.) Plainly, Respondents understood, through their counsel, that the cases were consolidated for pretrial proceedings, and that pretrial proceedings included both fact and expert discovery, as well as potential dispositive motions.

Moreover, if Respondents were correct that nothing was to happen that might affect the rights of anyone other than the ten test case plaintiffs, one must wonder why they did not object on that basis when Petitioners, as defendants below, pursued summary judgment against other plaintiffs based on the statute of limitations;[1] when Petitioners, as defendants below, pursued summary judgment against all plaintiffs based on a federal preemption argument;[2] or when Petitioners, as defendants below, pursued partial summary judgment as to the punitive damage claims of all plaintiffs.[3] Completely consistent with

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1. *See In re TMI*, 89 F.3d 1106 (3d Cir. 1996).

2. *See In re TMI*, 67 F.3d 1103 (3d Cir. 1995).

3. *See In re TMI*, 67 F.3d 1119 (3d Cir. 1995).

this history of consolidated activity, Petitioners, as defendants below, filed the motion for summary judgment directed against all plaintiffs, as soon as the *Daubert in limine* process (also directed against all plaintiffs) deprived all plaintiffs of the expert testimony proffered on their behalf, and essential to their claims.

Respondents attempt to evade the force of the Petition's soundness in other ways, equally mistaken. For example, they raise the false dichotomy that the proceedings below were either consolidated for all purposes, including trial, or for none. *Cf.* Brief in Opposition at 5. Since Petitioners agree that the cases were not consolidated for trial, *id.*, Respondents conclude that the cases could not have been consolidated for any "substantive" purposes, such as binding pretrial proceedings. That argument, however, represents the logical fallacy of the excluded middle. It is obviously possible (and common) that cases might be consolidated for pretrial proceedings, but not for trial.

Respondents also assert that under their trial plan, which the district court adopted, there was to be not just a bellwether trial, but "bellwether litigation" in which all proceedings were stayed as to everyone else. Brief in Opposition at 6. This characterization of events is belied by the fact that the order adopting the test case approach for trial said that a designated number of plaintiffs were to be selected "for an initial trial." That same order, however, also established a schedule for the completion of "all fact discovery" and "all expert discovery," and this portion of the order was expressly said by the district court to be applicable to "All Plaintiffs." Moreover, nothing in that (or any other) order stayed proceedings as to all plaintiffs other than the test case plaintiffs. Thus when Respondents assert that "the claims of the remaining 2000 plaintiffs [were]

essentially stayed pending the outcome of the bellwether cases", it is they who do not accurately portray what occurred in the district court.

At page 6 of the Brief in Opposition, Respondents contend:

> During the course of all of the pretrial proceedings, no suggestion was ever made by Petitioners that the administrative consolidation of the cases in fact affected [*sic*] a substantive consolidation that would affect the rights of the non-bellwether plaintiffs.

But the very same stipulation and order which effected the "administrative consolidation" (as Respondents like to call it)[4] is also the one which continued the procedure for using the captioning process to designate whether a pleading related to "All Plaintiffs" or only some subset of plaintiffs. And that procedure was used time and time again to affect the substantive "rights of the non-bellwether plaintiffs." As just noted, that procedure was used in connection with a summary judgment motion based on the statute of limitations and directed against 42 "non-bellwether" plaintiffs (which was granted), a summary judgment motion directed against all plaintiffs based on federal preemption of the standard of care (which was granted in part and denied in part), and a partial summary judgment motion directed against all plaintiffs relating to their claim for punitive damages (which was denied). Throughout this litigation, then, all of the plaintiffs in the consolidated cases knew they were

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4. Respondents never explain what limited function they understood the "administrative consolidation" to have served. Nor do they ever challenge the accuracy of Petitioners' recitation that at the time of the stipulation and order consolidating all the cases into one civil action, the then pending cases had already been consolidated for the purpose of pretrial proceedings.

"at risk" of being a target of pretrial proceedings which might affect their "substantive rights." Respondents' claim to the contrary is contradicted by years of proceedings, both in the trial court and the Court of Appeals.

In another egregious statement, the Brief in Opposition asserts (without furnishing any specifics or authority) that the captioning process *agreed to by the parties in a stipulation approved by the district court* cannot be invoked against Respondents because:

> In any event, substantive rights cannot be extinguished by a form over substance argument that works to the severe detriment to the substantive rights of the non-bellwether plaintiffs.

Brief in Opposition at 14. This can only be interpreted to mean that even though their counsel stipulated that the captioning procedure was to be the method by which the parties were to signal to each other whether a pleading (such as a summary judgment motion, for example) related to all plaintiffs or just a few plaintiffs, it is impermissible to use that agreed procedure that way if "substantive rights" might be affected. In other words, contrary to the rule that parties are bound by the acts and omissions of their legal representatives, Respondents assert that the rule cannot apply to *their* detriment.

But parties *are* bound by the acts of their counsel. As this Court said in a closely related context: "Petitioner voluntarily chose this attorney as his representative in the action, and he cannot now avoid the consequences of the acts or omissions of his freely selected agent. Any other notion would be wholly inconsistent with our system of representative litigation." *Pioneer Investment Services Co. v. Brunswick Associates, Ltd.*, 507 U.S. 380, 397; 113 S. Ct. 1489, 1499 (1993). Here, when

Respondents' counsel submitted the mandatory expert disclosures, they designated them as applying to "All Plaintiffs," not just ten "test case" or "bellwether" plaintiffs. It was those expert disclosures which set out the experts' theories on plaintiffs' radiation exposures, doses, and causation. Thus the Brief in Opposition is completely wrong when it asserts (at p. 15) that the "non-bellwether plaintiffs never acknowledged a minimum 10 rem threshold dose theory. . . ." That was precisely the theory advanced by a medical expert proffered on behalf of all plaintiffs.

Last, in closing their Statement of the Case, Respondents write:

> [I]n opposing [Petitioners'] request for summary judgment, they [the non-bellwether plaintiffs] presented evidence that established the existence of other legal and scientific theories that would permit their cases to be litigated irrespective of the exclusion of certain expert evidence proffered by the 10 bellwether plaintiffs. For example, the non-bellwether plaintiffs presented evidence that the scientific community recognizes that there is no safe threshold for exposure to radiation and the resulting induction of cancer.

Brief in Opposition at 16-17. But the "evidence" they refer to was evidence proffered as Exhibit 118 at the *in limine* hearings on the admissibility of plaintiffs' medical experts on causation. Thus, contrary to the claims elsewhere in the Brief in Opposition, here Respondents acknowledge that they *were participants in* the *in limine* process, *that they presented evidence* in those hearings, and that they *were participants in* the summary judgment process, opposing that motion with their own "legal and scientific theories."

In this context, it is simply incomprehensible how the Court of Appeals concluded that the Seventh Amendment required, in addition to service on Respondents' counsel of all the motion papers, that Respondents also had to supply a "positive manifestation of agreement" to be bound by the results of the *in limine* and summary judgment proceedings, before the district court could enter summary judgment against them. The question stated in the Petition is exactly the question presented in this case, and should be reviewed by this Court for exactly the reasons stated in the Petition. There is too much opportunity for mischief and inefficiency if the Court of Appeals' decision stands.

CONCLUSION

The petition for writ of certiorari should be granted.

Respectfully submitted,

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